REMARKS

I. PRELIMINARY REMARKS

Claims 45, 47, 52, 65, 68-70, 99 and 100 have been amended. Claims 102-103 have been added. Claims 66 and 98 have been canceled. Claims 45, 47, 48, 50-54, 65, 68-71, 73-81, 83-87, 89, 90, 92-97 and 99-103 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

On page 13, the Office Action indicates that claims 52-54 and 86 have been rejected based on the combined teachings of Umeda and Matsuura. Although claim 86 depends from independent claim 52, claims 53 and 54 do not. Claim 53 and 54 depend from independent claim 47, and independent claim 47 was not rejected based on the combined teachings of Umeda and Matsuura. Accordingly, applicant has assumed that the reference to claims 53 and 54 on page 3 was a typographical error ***and that no rejection has been applied to claims 53 and 54. Clarification of this issue is hereby requested. The November 14, 2008 Office Action included a similar error and applicant requested clarification in the April 14, 2009 amendment.***

II. REJECTIONS UNDER 35 U.S.C. §§ 102 AND 103

A. The Rejections

Claims 47, 48, 50, 51, 65, 66, 68-70, 73, 74, 80, 81, 87, 89, 90, 92-94 and 98-100 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,472,017 to Kovalcheck ("Kovalcheck").

Claims 45, 52, 79 and 86 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 5,255,668 to Umeda ("Umeda") and U.S. Patent No. 6,450,948 to Matsuura ("Matsuura"). Claims 75-78 and 83-85 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Umeda, Matsuura and U.S. Patent No. 5,507,725 to Savage ("Savage").

Claims 71, 95, 96 and 101 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Matsuura and Savage.

The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed to the extent that they are applicable to the claims as amended above. Reconsideration thereof is respectfully requested.

B. The Cited References

Kovalcheck is directed to a deflectable catheter system 20 which includes an insertion tube 24 with a bendable portion 26. [Figure 2.] Turning to Figures 11 and 12, the bendable portion 26 includes a working channel 44, an outer covering 128 and a coil spring 132 located between the working channel 44 and the outer covering 128. The coil spring 132 has a proximal end 133 as well as tightly wound sections 134a-c that are respectively connected to two sets of pull wires 110a-c. A pair of splines 137, which are attached to the spring 132, ***are offset from the sets of steering wires 110a-c by 90 degrees***. To that end, Kovalcheck indicates that the splines 137 "attach to the tightly wound section on both sides of the spring along the neutral axis" and "prevent compression of the coil spring 132 while ***adding negligible bending stiffness due to their position along the neutral axis***." [Col. 12, ll. 37-47.]

FIG. 11

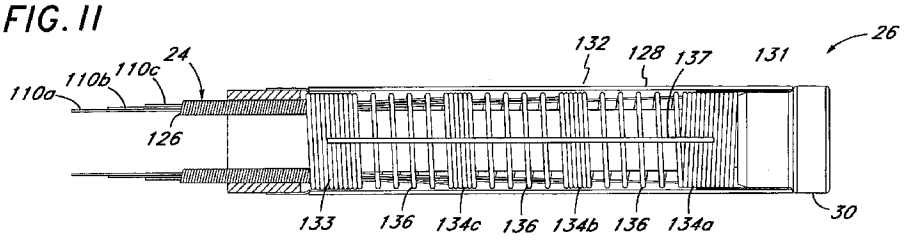
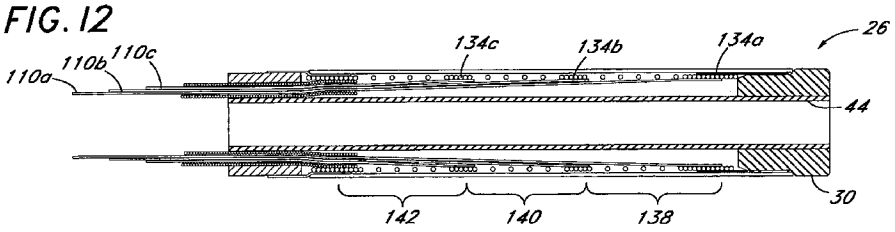


FIG. 12



Umeda discloses a bending device that may be used in an endoscope or catheter. Referring to Figures 1 and 2, the illustrated endoscope includes a hollow body 1, with an

insertion portion 2 and a bending portion 3, and a pair of wires 8a/8b that are used to deflect the bending portion. [Column 3, lines 28-32 and 56-65.] The bending portion 3 has a bending device 9. The bending device 9 includes a thin plate 10, a coil 20, a tip member 30, a connecting tube 40 that connects the coil to the tip member, and a connecting tube 50 that connects the coil to the insertion portion 2. The connecting tubes 40 and 50 include slits 42a/42b and 51a/51b for the thin plate 10. The connecting tube 40 also includes an extra set of slits 41a/41b that allow the distal ends of the wires 8a/8b to secured to the connecting tube 40. [Column 6, line 62 to column 7, line 7.]

Matsuura discloses a variety of deflectable tips for use with steerable surgical instruments. The instrument illustrated in Figures 1-5 includes a delectable tip section 40. The delectable tip section 40 includes proximal and distal collars 50A and 50B on opposite ends of a flexible tubular body 52. A pair of strengthening members 54 are positioned within the wall of the tubular body 52 and extend from the end collar 50A to the end collar 50B. The deflectable tip is illustrated in Figures 11 and 12 was also referred to in the Office Action. Here too, the deflectable tip includes collars 350A and 350B, a tubular body 352, and strengthening members 354A and 354B. Turning to Figure 22d, Matsuura also discloses that collars 1150A/1150B and ribs 1164 (in an alternative tip section) may be provided with grooves 1165 for a pull wire.

Savage discloses that certain structures (e.g. anchoring rings 22) may be located within a catheter wall. [Column 6, lines 16-61.]

C. Discussion Concerning Claims 45 and 75-79

Independent claim 45 calls for a combination of elements including, *inter alia*, "an elongate body defining a proximal portion and a distal portion," "a steering wire having a distal portion," "an anchoring member" and "means, directly connected to the anchoring member, for preventing compression …" and "a tubular member, that is a partial circle in cross-section and includes first and second longitudinally extending edges that together ***define a slot, which extends completely through the tubular member at the first and second edges, in which a portion of the steering wire is located*** …"

The respective combinations defined by claims 75-79 include, *inter alia*, the elements recited in claim 45.

The cited references fail to teach or suggest the claimed combinations. For example, the Office Action asserted that (1) one of the Umeda wires 8a/8b corresponds to the claimed "steering wire," (2) a portion of the Umeda connecting tube 50 corresponds to the claimed "tubular member," and (3) the interior passage of connecting tube 50 corresponds to the claimed "slot," albeit one that is not "defined by first and second longitudinally extending edges." The Office Action further asserted that the teachings of Matsuura, i.e. the ***groove*** 1165 in collar 1150B, would have led one of skill in the art to form a ***slot*** "defined by first and second longitudinally extending edges" in the Umeda connecting tube 50.

There are a number of shortcomings associated with the Umeda/Matsuura combination. The Matsuura groove 1165 ***does not extend completely through*** the collar 1150B at the edges thereof. As such, even assuming that there was some reason to combine the Umeda and Matsuura teachings, the result is not the claimed combination. It should also be noted that the result of the purportedly obvious modification of Umeda, i.e. the addition the Matsuura ***exterior side*** groove to the Umeda connecting tube 50, would result in the wires 8a/8b being ***located outside*** the coil 20 and connecting tube 50. The Office Action failed to indicate why a skilled artisan would have moved the wires 8a/8b outside the coil 20.

As Umeda and Matsuura fail to teach or suggest the combination of elements recited in independent claim 45, applicant respectfully submits that the rejection of claims 45 and 79 under 35 U.S.C. § 103 should be withdrawn.

With respect to claims 75-78, applicant respectfully submits that Savage fails to remedy the above-identified deficiencies in Umeda and Matsuura. As such, the rejection of claims 75-78 under 35 U.S.C. § 103 should also be withdrawn.

D. Discussion Concerning Claims 47, 48, 50, 51, 80 and 81

At the outset, applicant notes that claim 47 now calls for the combination of elements previously recited in now-canceled dependent claim 66.

Independent claim 47 calls for a combination of elements including, *inter alia*, "an elongate body," "a stiffening member associated with the distal portion of the elongate body and located within the elongate body wall" and "an anti-tear device positioned within the elongate body wall." Claim 47 also indicates that "***the stiffening member and the distal portion of the steering wire are substantially diametrically opposed from one another***." The respective combinations defined by claims 48, 50, 51, 80 and 81 include, *inter alia*, the elements recited in claim 47.

Kovalcheck fails to teach or suggest the claimed combinations. The Office Action has taken the position that one of the Kovalcheck pull wires 110a corresponds to the claimed "steering wire" and that one of the Kovalcheck splines 137 corresponds to the claimed "stiffening member." [Office Action at pp. 2-3.] Even assuming for the sake of argument that this is a reasonable interpretation of the claims, there is no diametrically opposed pull wire 110a and spline 137.[1] To the contrary, the each pull wire is offset by 90 degrees from the splines 137.

As Kovalcheck fails to teach or suggest each and every element of the combination recited in independent claim 47, applicant respectfully submits that the rejection of claims 47, 48, 50, 51, 80 and 81 under 35 U.S.C. § 102 should be withdrawn.

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[1] Applicant notes here that two elements are "diametrically opposed" if they are directed opposite each other on a circle, i.e. are on opposite ends of a diameter. Put another way, two elements are "diametrically opposed" if they are displaced from one another by 180 degrees about a circle. Additionally, to the extent that there is any question as to how one of skill in the art would interpret "diametrically opposed," the Examiner's attention is directed to, for example, Fig. 17 and col. 20, ll. 10-29 of U.S. Pat. No. 6,045,550 (Exhibit 1); Fig. 17 and col. 12, ll. 1-2 of Savage (of record); Fig. 13 and col. 8, ll. 61-66 of U.S. Pat. No. 5,464,395 (Exhibit 2); and Fig. 5 and col. 8, ll. 5-12 of U.S. 5,676,653 (Exhibit 3). It should also be noted that Matsuura (of record) uses the similar phrase "diametrically opposite" to mean the same thing as "diametrically opposed." [Note Fig. 3 and col. 3, ll. 64-66.]

E. Discussion Concerning Claims 52 and 83-86

Independent claim 52 calls for a combination of elements including, *inter alia*, "an elongate body," "a steering wire," "a stiffening member associated with the distal portion of the elongate body" and "a substantially c-shaped anti-tear device, including first and second longitudinally extending edges that together define ***a slot which extends completely through the tubular member at the first and second edges***, associated with the stiffening member." Claim 52 also indicates that "a portion of the steering wire is positioned within the slot." The respective combinations defined by claims 83-86 include, *inter alia*, the elements recited in claim 52.

The cited references fail to teach or suggest the claimed combinations. For example, the Office Action asserted that (1) one of the Umeda wires 8a/8b corresponds to the claimed "steering wire," (2) a portion of the Umeda connecting tube 50 corresponds to the claimed "tubular member," and (3) the interior passage of connecting tube 50 corresponds to the claimed "slot," albeit one that is not "defined by first and second longitudinally extending edges." The Office Action further asserted that the teachings of Matsuura, i.e. the ***groove*** 1165 in collar 1150B, would have led one of skill in the art to form a ***slot*** "defined by first and second longitudinally extending edges" in the Umeda connecting tube 50.

There are a number of shortcomings associated with the Umeda/Matsuura combination. The Matsuura groove 1165 ***does not extend completely through*** the collar 1150B at the edges thereof. As such, even assuming that there was some reason to combine the Umeda and Matsuura teachings, the result is not the claimed combination. It should also be noted that the result of the purportedly obvious modification of Umeda, i.e. the addition the Matsuura ***exterior side*** groove to the Umeda connecting tube 50, would result in the wires 8a/8b being ***located outside*** the coil 20 and connecting tube 50. The Office Action failed to indicate why a skilled artisan would have moved the wires 8a/8b outside the coil 20.

As Umeda and Matsuura fail to teach or suggest the combination of elements recited in independent claim 52, applicant respectfully submits that the rejection of claims 52 and 86 under 35 U.S.C. § 103 should be withdrawn.

With respect to claims 83-85, applicant respectfully submits that Savage fails to remedy the above-identified deficiencies in Umeda and Matsuura. As such, the rejection of claims 83-85 under 35 U.S.C. § 103 should also be withdrawn.

F. Discussion Concerning Claims 65 and 87

Independent claim 65 calls for a combination of elements including, *inter alia*, "an elongate body defining a proximal portion and a distal portion and including a wall defining an inner surface, an outer surface and a lumen," "a steering wire," "a stiffening member" and "an anti-tear device." Claim 65 also indicates that "***the steering wire ... is substantially diametrically opposed to the stiffening member***." The combination defined by claim 87 includes, *inter alia*, the elements recited in claim 65.

Kovalcheck fails to teach or suggest the claimed combinations. The Office Action has taken the position that one of the Kovalcheck pull wires 110a corresponds to the claimed "steering wire" and that one of the Kovalcheck splines 137 corresponds to the claimed "stiffening member." [Office Action at p. 4.] Even assuming for the sake of argument that this is a reasonable interpretation of the claims, there is no diametrically opposed pull wire 110a and spline 137. To the contrary, the each pull wire is offset by 90 degrees from the splines 137.

As Kovalcheck fails to teach or suggest each and every element of the combination recited in independent claim 65, applicant respectfully submits that the rejection of claims 65 and 87 under 35 U.S.C. § 102 should be withdrawn.

G. Discussion Concerning Claim 68, 89 and 90

At the outset, applicant notes that claim 68 now calls for the combination of elements previously recited in now-canceled dependent claim 98.

Independent claim 68 calls for a combination of elements including, *inter alia*, "an elongate body ... including a wall defining an inner surface, an outer surface and a lumen," "a stiffening member associated with the distal portion of the elongate body" and "anti-tear means." Claim 68 also indicates that "the stiffening member and the distal portion of the steering wire ***are offset from one another by about 180 degrees*** about the longitudinal axis." The respective combinations defined by claims 89 and 90 include, *inter alia*, the elements recited in claim 68.

Kovalcheck fails to teach or suggest the claimed combinations. The Office Action has taken the position that one of the Kovalcheck pull wires 110a corresponds to the claimed "steering wire" and that one of the Kovalcheck splines 137 corresponds to the claimed "stiffening member." [Office Action at p. 6.] Even assuming for the sake of argument that this is a reasonable interpretation of the claims, there is no pull wire 110a and spline 137 that are offset by about 180 degrees. To the contrary, the each pull wire is offset by 90 degrees from the splines 137.

As Kovalcheck fails to teach or suggest each and every element of the combination recited in independent claim 68, applicant respectfully submits that the rejection of claims 68, 89 and 90 under 35 U.S.C. § 102 should be withdrawn.

H. Discussion Concerning Claims 69, 70, 73, 74, 92-94, 99 and 100

Independent claims 69 and 70 call for respective combinations of elements including, *inter alia*, "an elongate body defining ... a distal portion and including a ***substantially solid*** wall defining an inner surface, an outer surface and a lumen," "a steering wire" and "an anchoring member located within the distal portion of the ***substantially solid*** elongate body wall between the inner surface and the outer surface and secured to the steering wire." The combinations defined by claims 73, 74, 92 and 99 include, *inter alia*, the elements recited in claim 69, and the combinations defined by claims 93, 94 and 100 include, *inter alia*, the elements recited in claim 70.

Kovalcheck fails to teach or suggest the claimed combinations. For example, the Office Action has taken the position that the Kovalcheck working channel 44 and the outer

covering 128 together form a wall. In contrast to the claimed combinations, however, the Kovalcheck working channel 44 and the outer covering 128 together ***form a hollow wall, not a "substantially solid" wall***.

As Kovalcheck fails to teach or suggest each and every element of the respective combinations recited in independent claims 69 and 70, applicant respectfully submits that the rejection of claims 69, 70, 73, 74, 92-94, 99 and 100 under 35 U.S.C. § 102 should be withdrawn.

I. Discussion Concerning Claims 71, 95, 96 and 101

Independent claim 71 calls for a combination of elements including, *inter alia*, "an elongate body defining ... a distal portion and including a wall defining an inner surface, an outer surface and a lumen," "a steering wire" and "an ***anchoring member located within the distal portion of the elongate body wall between the inner surface and the outer surface*** and secured to the steering wire." The combinations defined by claims 95, 96 and 101 include, *inter alia*, the elements recited in claim 71.

The Office Action failed to establish a *prima facie* case of obviousness of the claimed combinations. For example, the Office Action asserted that (1) the Matsuura distal collar 50B (or 350B), which is not located within an elongate body wall, corresponds to the claimed "anchoring member" and (2) Savage would have suggested modifications to the Matsuura device that would have resulted in the Matsuura distal collar 50B (or 350B) being moved into an elongate body wall. Applicant respectfully submits that assertion (2) is incorrect. While it is true that Savage discloses the placement of various structures within an elongate body, none of those structures define the distal end of the device, as does the Matsuura distal collar. Accordingly, Savage would not have suggested moving the Matsuura distal collar into the elongate body wall.

Faced with deficiency in cited references, the Office Action proposed the following "reason" for modification of the Matsuura:

> [I]t would have been obvious to use the teachings of Savage to place Matsuura's device within a body wall as this would further strengthen the bond between the tubular members at either end and

> the middle section. A layer formed over the bonding points would prevent any premature breakage of the bonding points and thus make the device stronger and last longer.

[Office Action at p. 18.] Applicant respectfully submits that the "reason" proposed in the Office Action is wholly unpersuasive because it ignores the fact that distal collar 50B is secured to the proximal collar 50A by a pair of strengthening members 54. As such, the proposed modification would add complexity to the manufacturing process for what appears to be no beneficial result. The proposed modification would also result in either a reduction of thickness of the distal collar 50B, an increase in diameter of the device, or a reduction in the diameter of the internal lumen. The Office Action failed to address why, given the results of the proposed modification, a skill artisan would have been motivated to make the modification.

As illustrated above, Matsuura and Savage fail to establish a *prima facia* case of obviousness with respect to the invention defined by independent claim 71. The rejection of claims 71, 95, 96 and 101 under 35 U.S.C. § 103 should, therefore, be withdrawn.

III. NEWLY PRESENTED CLAIMS 102 AND 103

Newly presented claim 102 depends from independent claim 69 and is patentable for at least the same reasons as claim 69.

Newly presented claim 103 depends from independent claim 70 and is patentable for at least the same reasons as claim 70.

IV. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned

representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

October 21, 2009
Date

/Craig A. Slavin/
Craig A. Slavin
Reg. No. 35,362
Attorney for Applicant

Henricks, Slavin & Holmes LLP
840 Apollo Street, Suite 200
El Segundo, CA 90245
(310) 563-1458, (310) 563-1460 (Facsimile)

EXHIBIT 1

US006045550A

United States Patent [19]

Simpson et al.

[11] **Patent Number: 6,045,550**

[45] **Date of Patent: Apr. 4, 2000**

[54] **ELECTRODE HAVING NON-JOINED THERMOCOUPLE FOR PROVIDING MULTIPLE TEMPERATURE-SENSITIVE JUNCTIONS**

[75] Inventors: **John A. Simpson**, Carlsbad; **Marshall L. Sherman**, Cardiff, both of Calif.

[73] Assignee: **Cardiac Peacemakers, Inc.**, St. Paul, Minn.

[21] Appl. No.: **09/072,853**

[22] Filed: **May 5, 1998**

[51] **Int. Cl.**[7] **A61B 17/39**

[52] **U.S. Cl.** **606/42**; 606/31; 606/41; 607/102; 600/549

[58] **Field of Search** 606/31–35, 41, 606/42, 45–50; 607/101, 102; 600/549, 374

[56] **References Cited**

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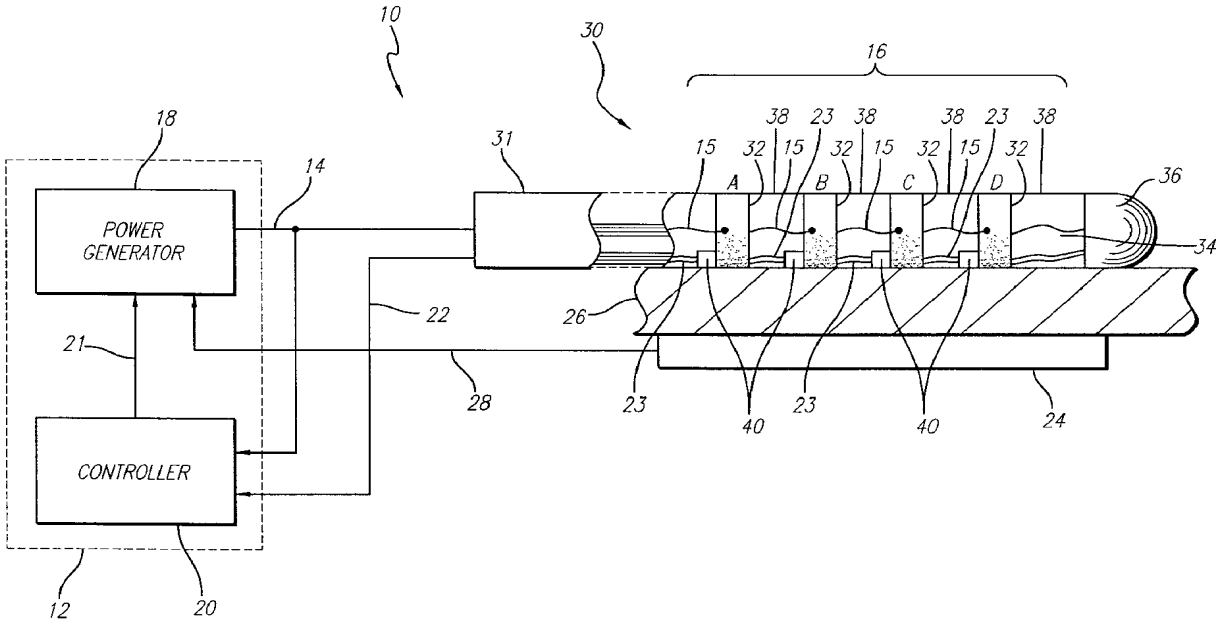
Primary Examiner—Michael Peffley

Attorney, Agent, or Firm—Fulwider Patton Lee & Utecht, LLP

[57] **ABSTRACT**

The non-joined thermocouple electrode configuration, for use in an RF ablation catheter for ablating biological tissue such as cardiac tissue, allows temperature to be monitored at two locations of a band electrode while only using a single pair of thermocouple wires. The thermocouple wires are connected to the electrode at separate locations. They preferably are formed of metallic materials having Seebeck coefficients that are substantially equal in magnitude but opposite in sign relative to the electrode material connecting the two. In the case of a band electrode, the two thermocouple wires are preferably spaced apart on the band electrode so that the first junction contacts the tissue having a first temperature and the second junction contacts circulating blood having a second temperature. The voltage across the thermocouple wires provides an indication of the average of the two junctions temperatures so that by monitoring the temperature of the blood, the temperature of the first junction can be determined from this average temperature.

39 Claims, 16 Drawing Sheets



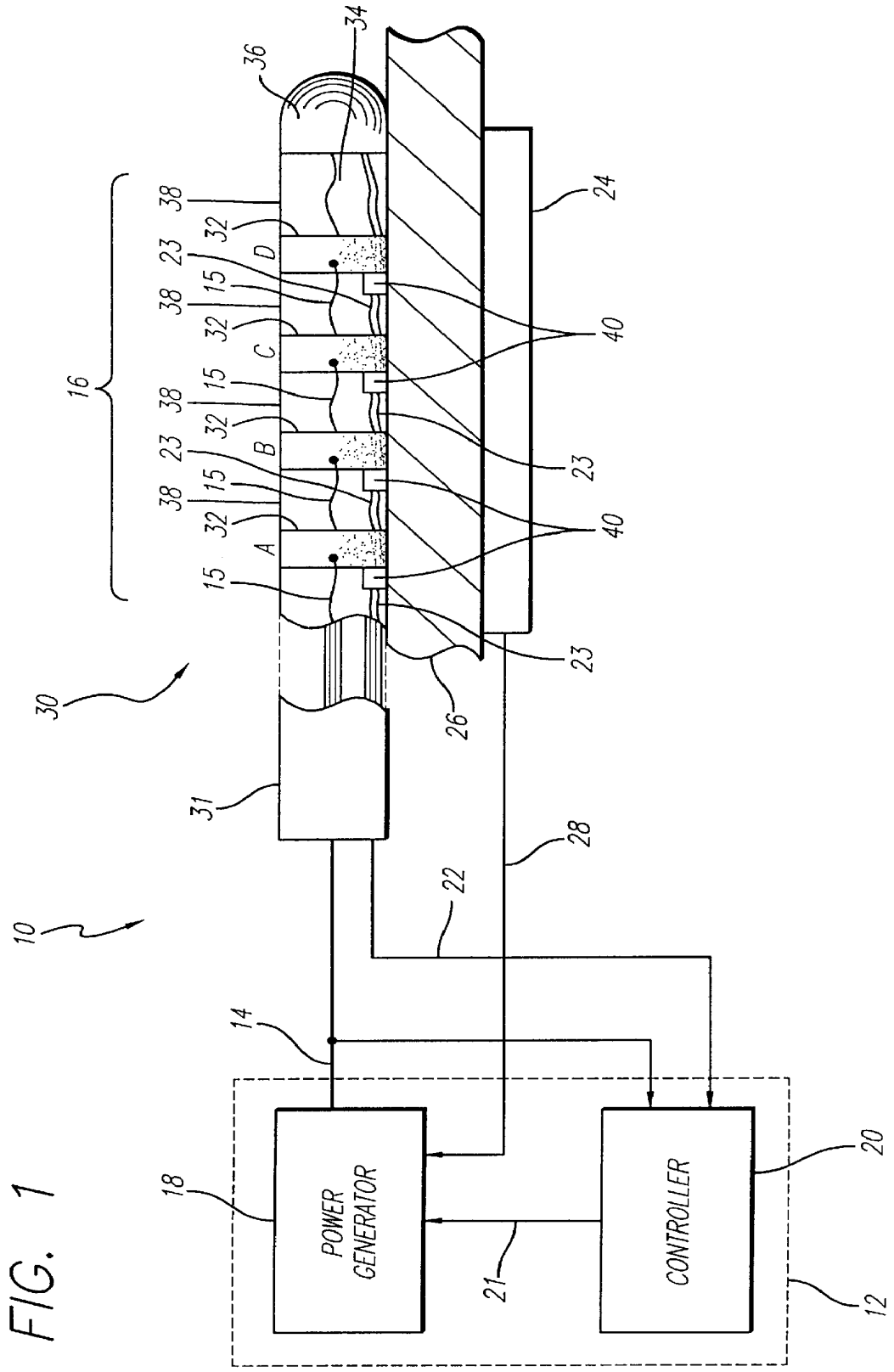

POWER GENERATOR
CONTROLLER
10
12
14
15
16
18
20
21
22
23
24
26
28
30
31
32
34
36
38
40
A
B
C
D

FIG. 1

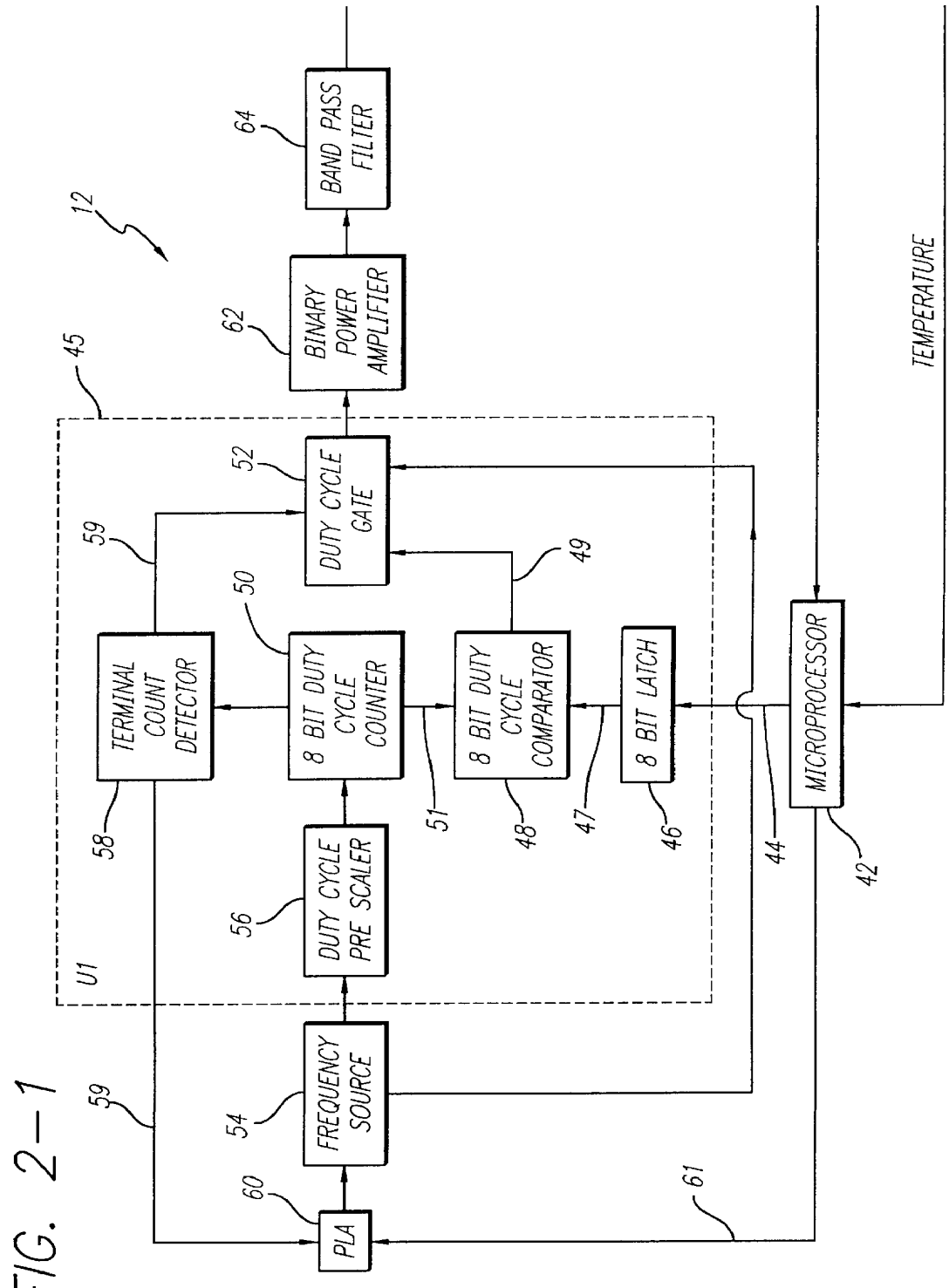

12
64
BAND PASS FILTER
62
BINARY POWER AMPLIFIER
45
52
DUTY CYCLE GATE
59
50
49
TERMINAL COUNT DETECTOR
8 BIT DUTY CYCLE COUNTER
8 BIT DUTY CYCLE COMPARATOR
8 BIT LATCH
MICROPROCESSOR
TEMPERATURE
58
56
DUTY CYCLE PRE SCALER
51
48
47
46
44
42
U1
59
54
FREQUENCY SOURCE
60
PLA
61

FIG. 2-1

FIG. 2-2

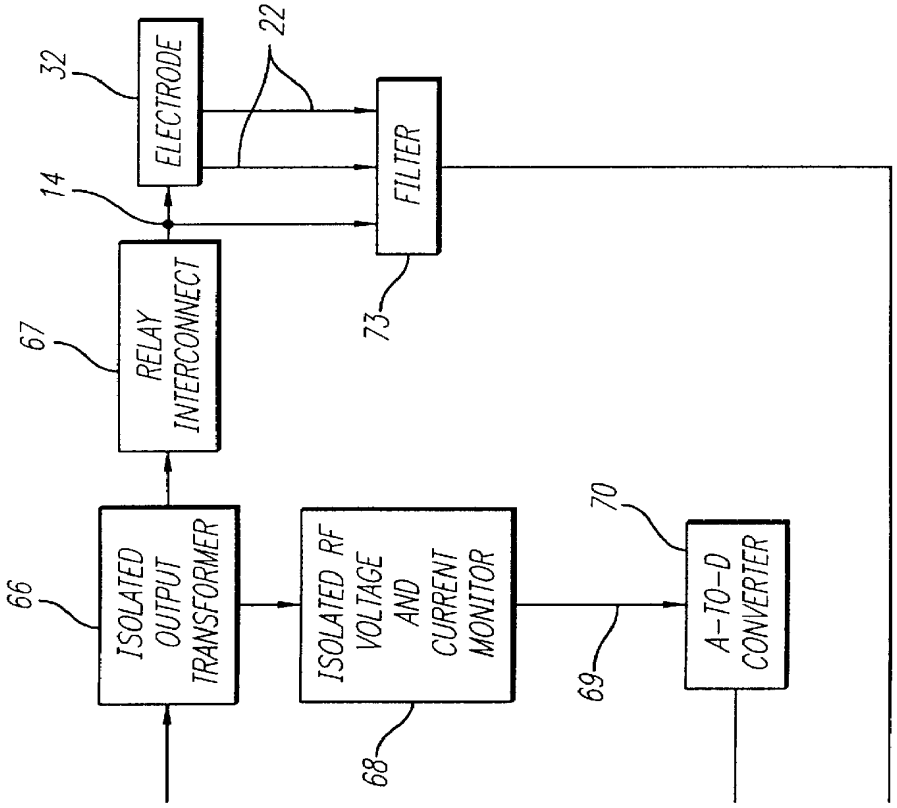

ELECTRODE
32
22
FILTER
14
RELAY INTERCONNECT
67
73
ISOLATED OUTPUT TRANSFORMER
66
ISOLATED RF VOLTAGE AND CURRENT MONITOR
68
70
A-TO-D CONVERTER
69

FIG. 3

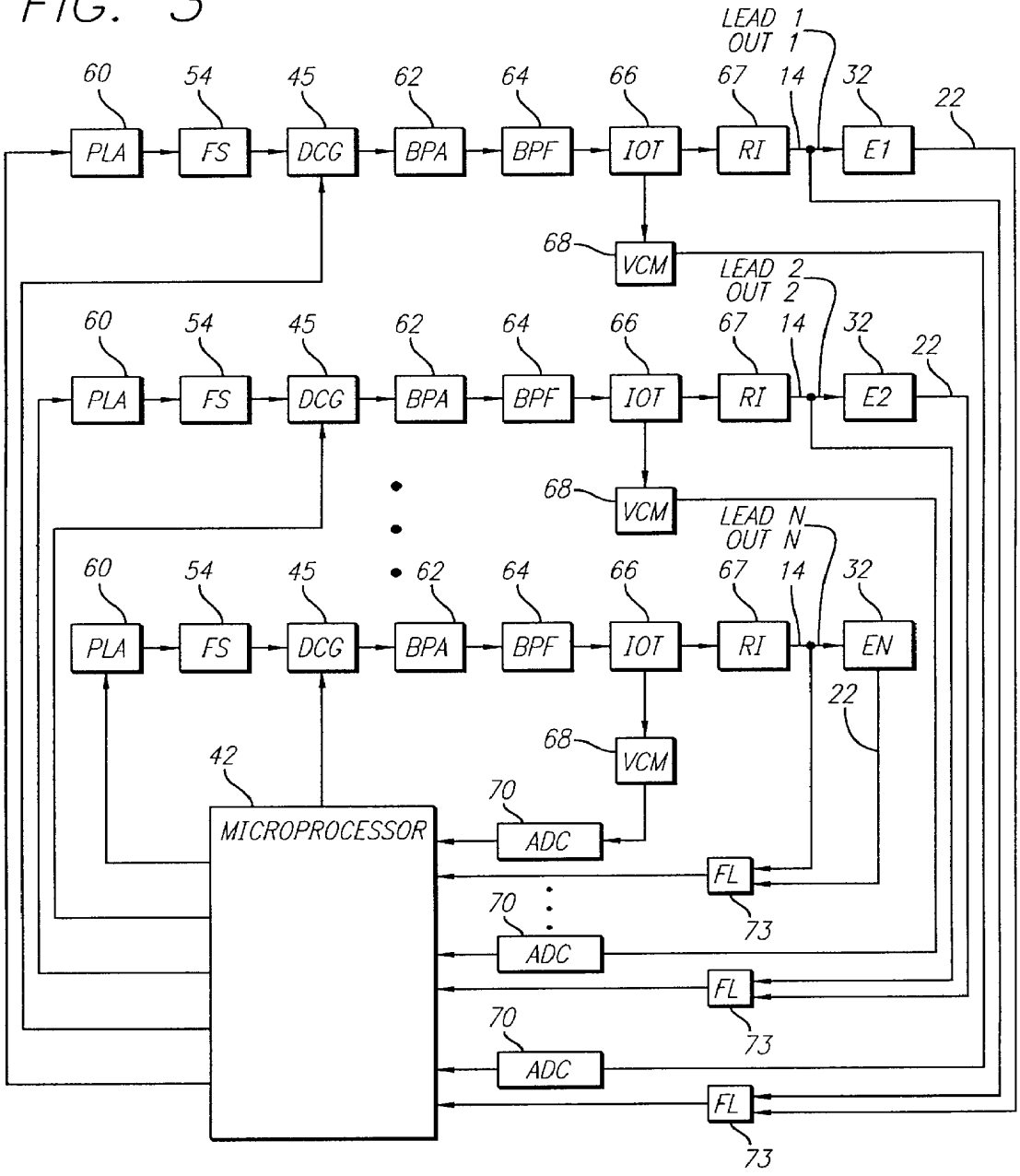
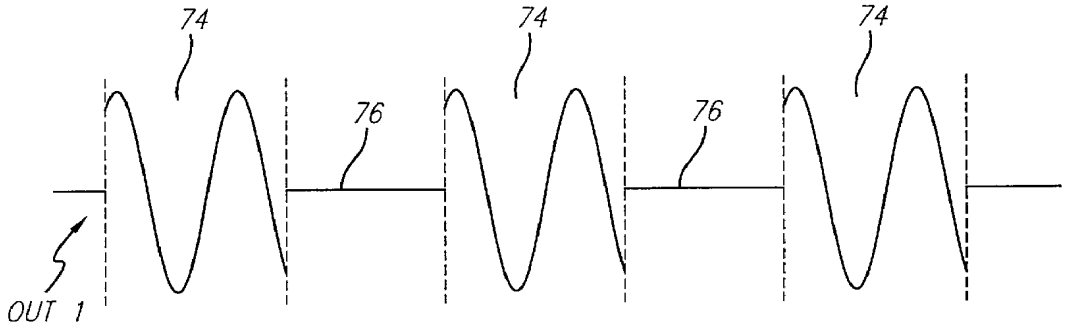

LEAD 1 OUT 1
LEAD 2 OUT 2
LEAD N OUT N
60
54
45
62
64
66
67
14
32
22
PLA
FS
DCG
BPA
BPF
IOT
RI
E1
E2
EN
68
VCM
42
MICROPROCESSOR
70
ADC
FL
73

FIG. 4



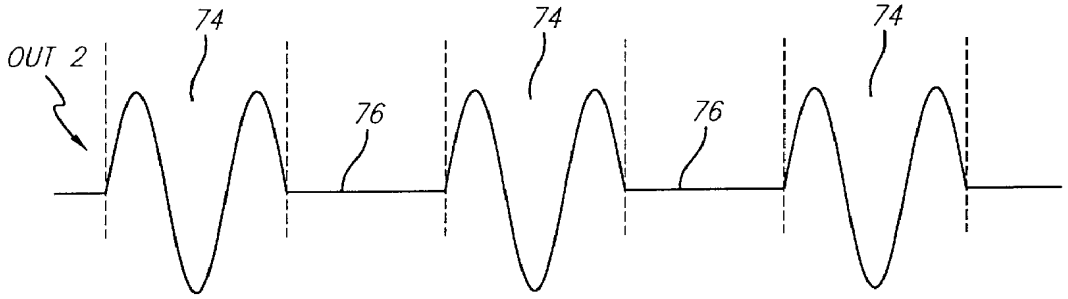


FIG. 5

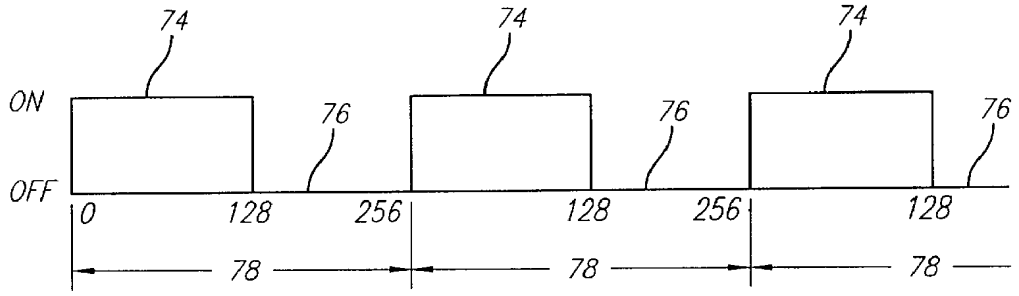


FIG. 6

FIG. 7A

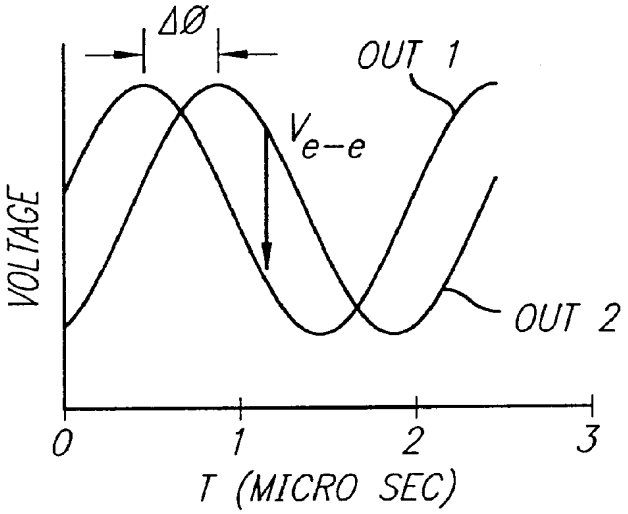
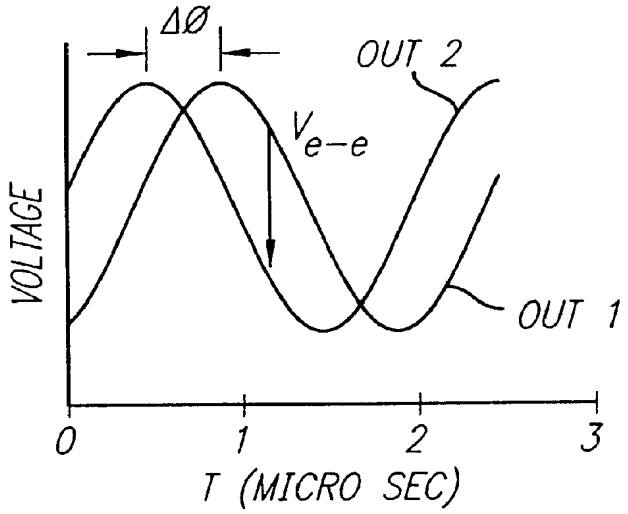

ΔØ
OUT 1
V_{e-e}
VOLTAGE
OUT 2
0
1
2
3
T (MICRO SEC)

FIG. 7B


ΔØ
OUT 2
V_{e-e}
VOLTAGE
OUT 1
0
1
2
3
T (MICRO SEC)

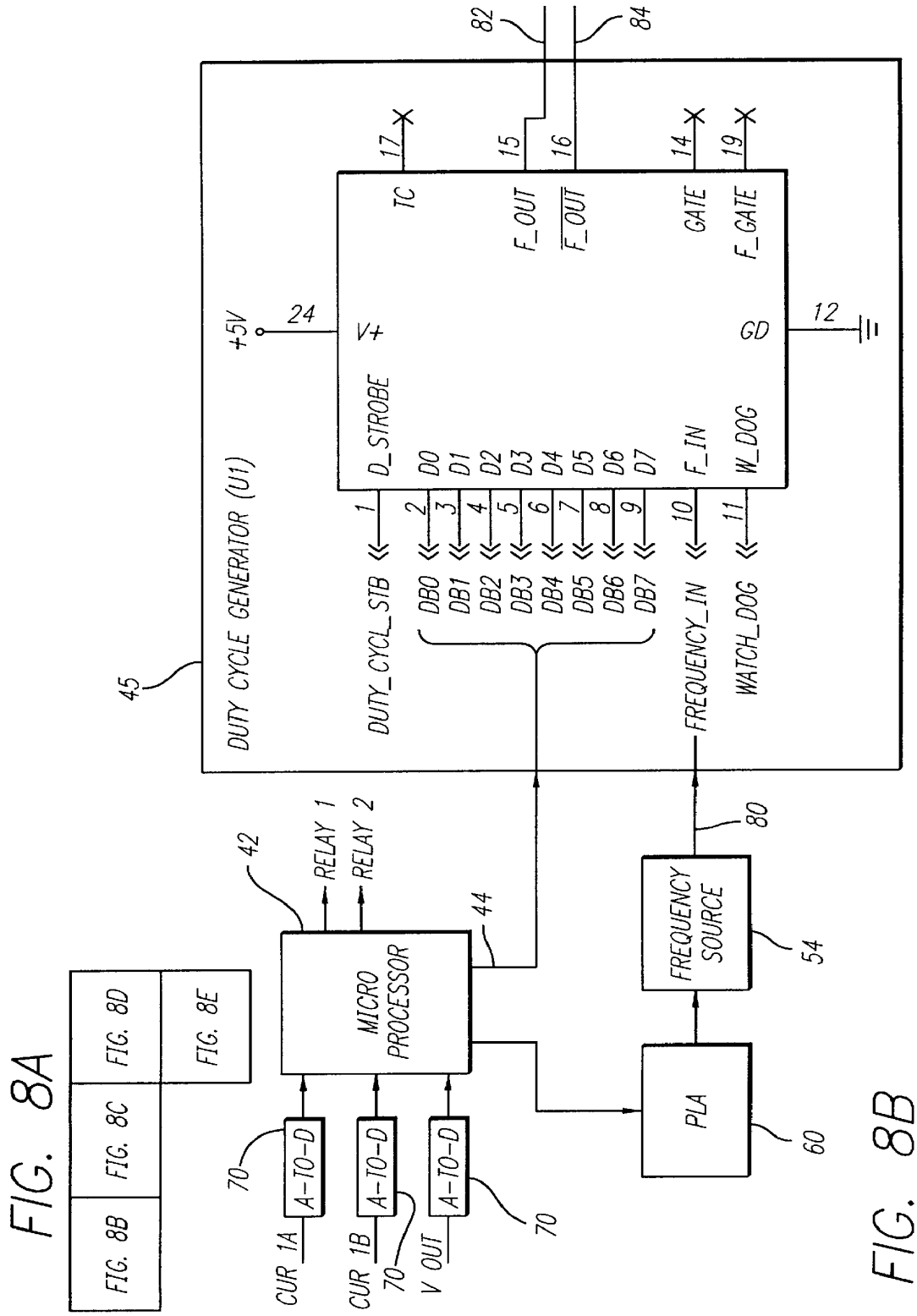

82
84
17
15
16
14
19
TC
F_OUT
F_OUT
GATE
F_GATE
+5V
24
V+
GD
12
D_STROBE
D0
D1
D2
D3
D4
D5
D6
D7
F_IN
W_DOG
1
2
3
4
5
6
7
8
9
10
11
DUTY_CYCL_STB
DB0
DB1
DB2
DB3
DB4
DB5
DB6
DB7
FREQUENCY_IN
WATCH_DOG
45
DUTY CYCLE GENERATOR (U1)
42
RELAY 1
RELAY 2
44
MICRO PROCESSOR
80
FREQUENCY SOURCE
54
PLA
60
70
A-TO-D
CUR 1A
CUR 1B
V OUT
70
70

FIG. 8A

FIG. 8B
FIG. 8C
FIG. 8D
FIG. 8E

FIG. 8B

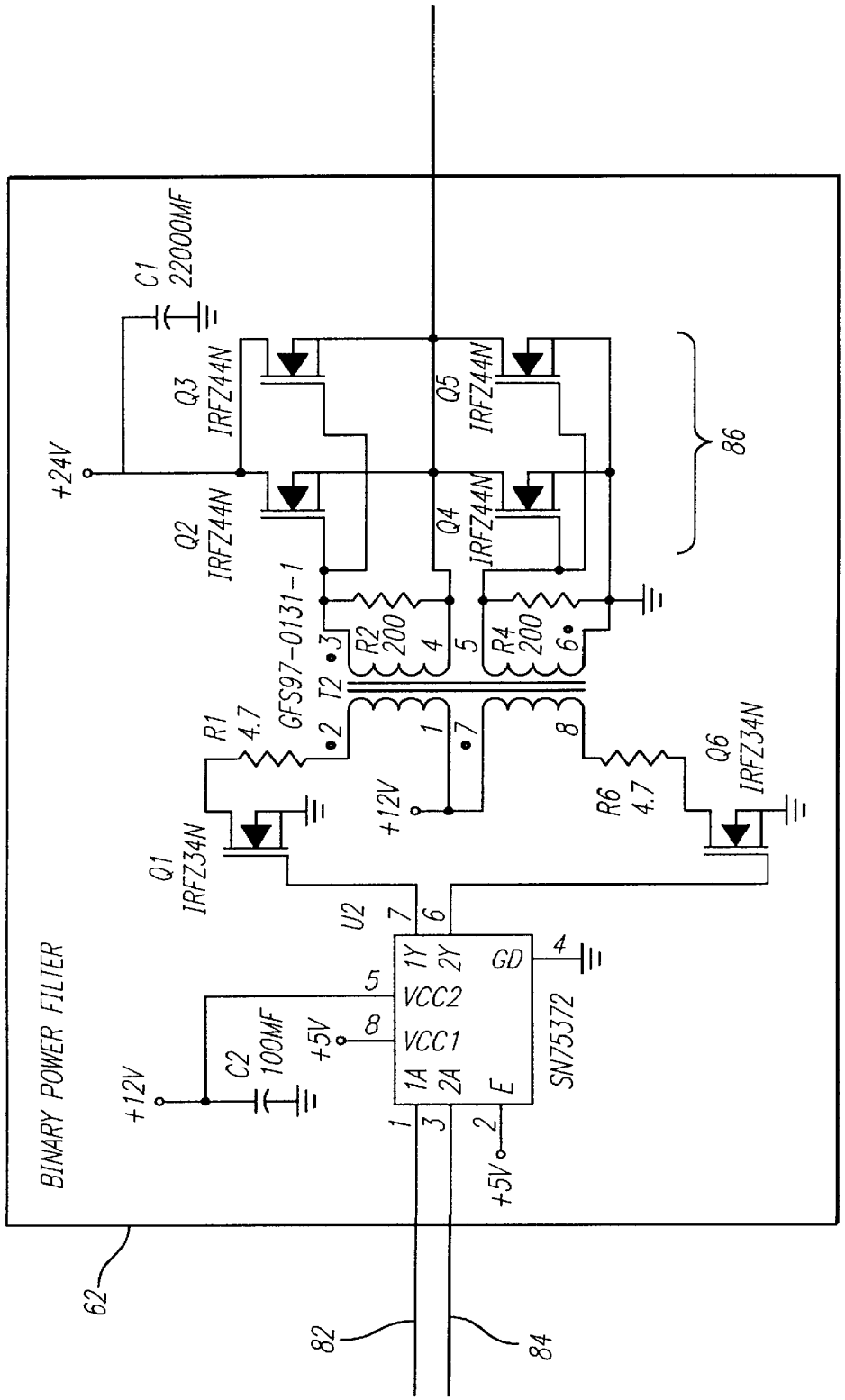

BINARY POWER FILTER
62
C1
2200OMF
+24V
Q3
IRFZ44N
Q5
IRFZ44N
Q2
IRFZ44N
Q4
IRFZ44N
86
GFS97-0131-1
T2
R2
200
R4
200
R1
4.7
R6
4.7
Q1
IRFZ34N
Q6
IRFZ34N
+12V
U2
1Y
2Y
GD
VCC2
VCC1
1A
2A
E
SN75372
C2
100MF
+5V
82
84

FIG. 8C

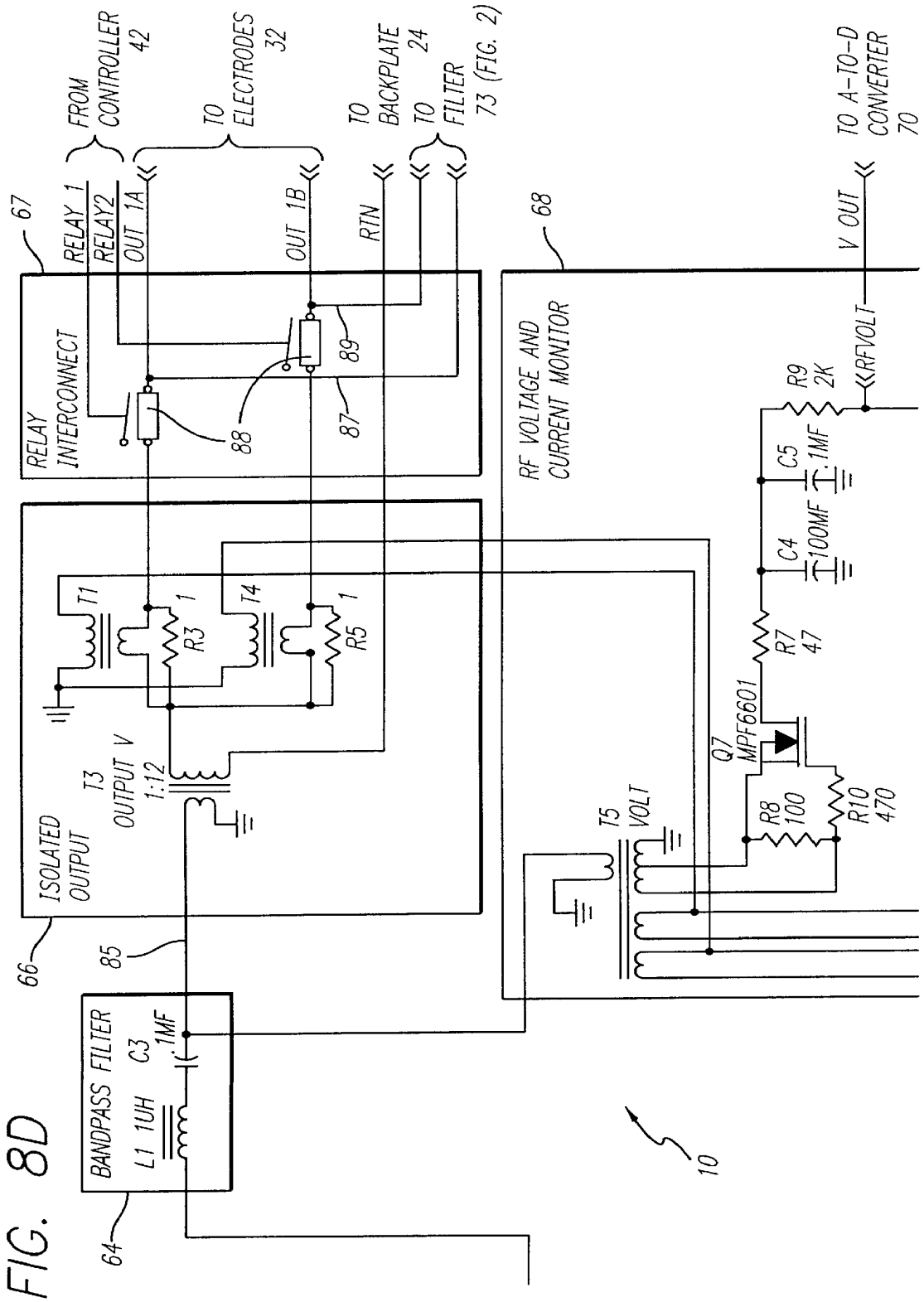

FROM CONTROLLER 42
TO ELECTRODES 32
TO BACKPLATE 24
TO FILTER 73 (FIG. 2)
TO A-TO-D CONVERTER 70
67
RELAY 1
RELAY2
OUT 1A
OUT 1B
RTN
V OUT
68
RELAY INTERCONNECT
88
89
87
RF VOLTAGE AND CURRENT MONITOR
RFVOLT
R9 2K
C5 1MF
C4 100MF
T1
R3 1
T4
R5 1
R7 47
Q7 MPF6601
T3 OUTPUT V 1:12
T5 VOLT
R8 100
R10 470
ISOLATED OUTPUT
66
85
BANDPASS FILTER
L1 1UH
C3 1MF
64
10

FIG. 8D

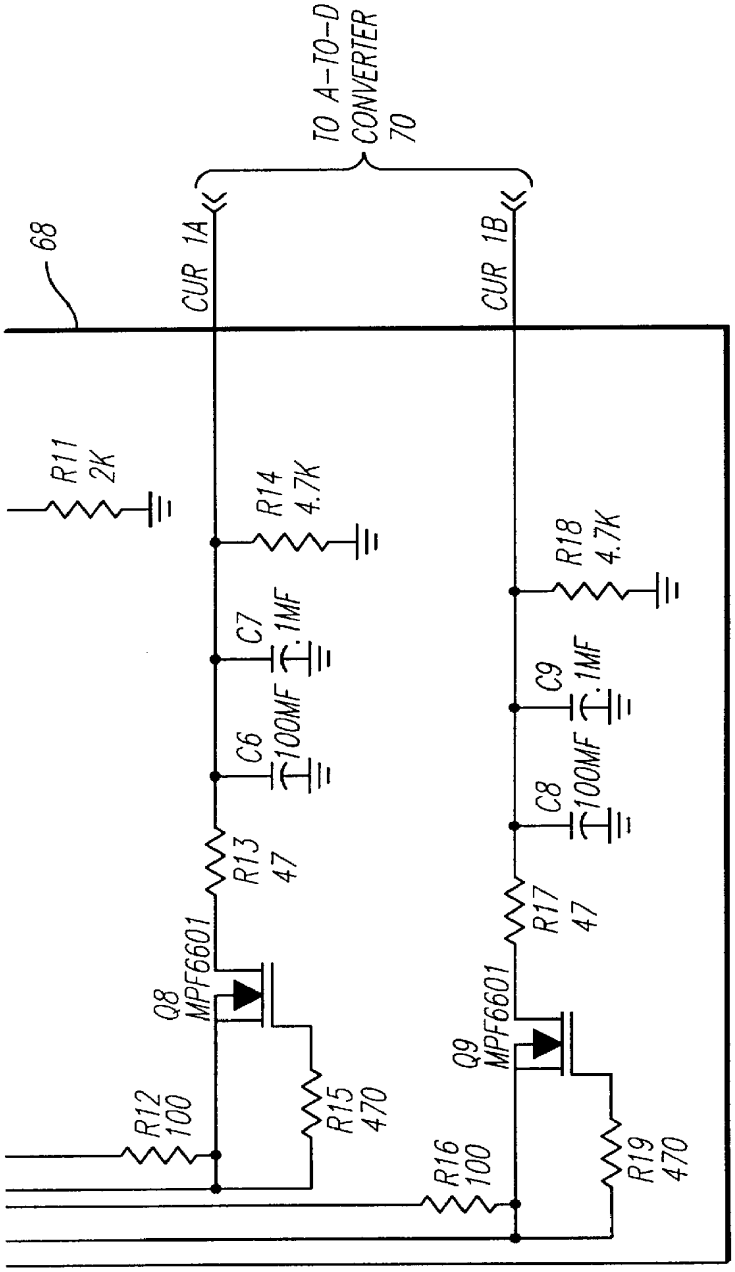

TO A-TO-D CONVERTER 70
68
CUR 1A
CUR 1B
R11 2K
R14 4.7K
R18 4.7K
C7 .1MF
C6 100MF
C9 .1MF
C8 100MF
R13 47
R17 47
Q8 MPF6601
Q9 MPF6601
R12 100
R15 470
R16 100
R19 470

FIG. 8E

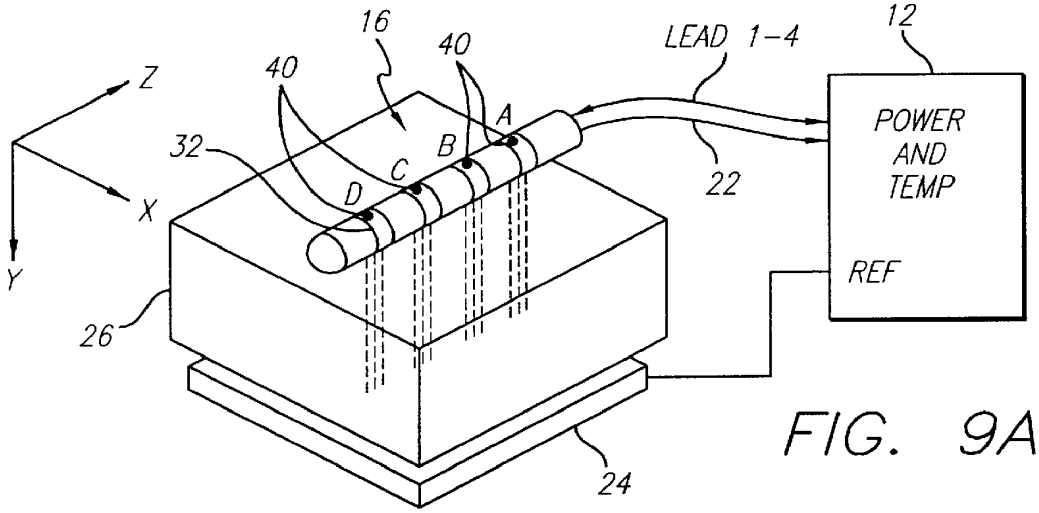


FIG. 9A

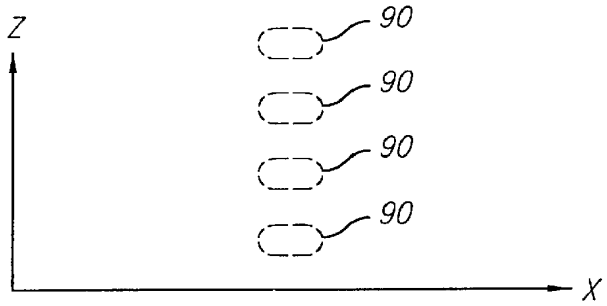


FIG. 9B

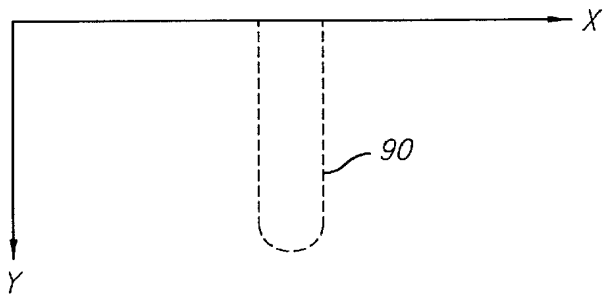


FIG. 9C

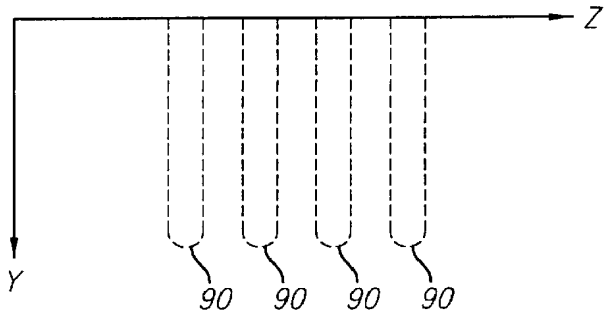


FIG. 9D

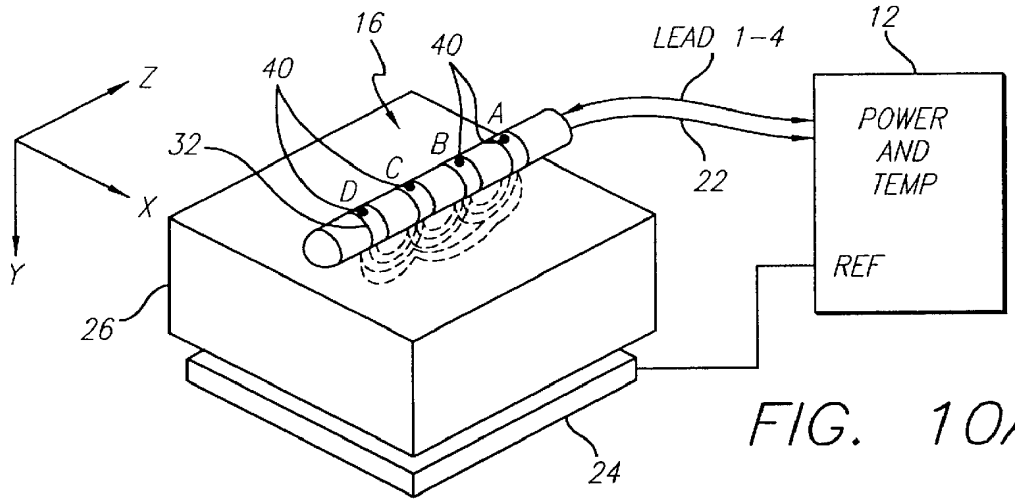


FIG. 10A

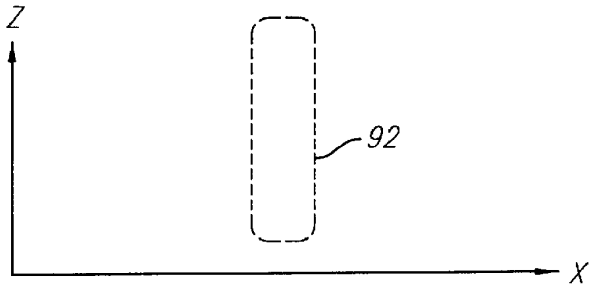


FIG. 10B

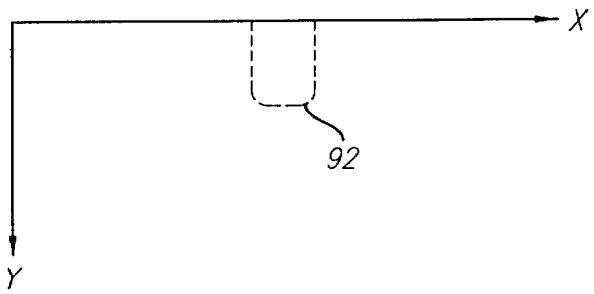


FIG. 10C

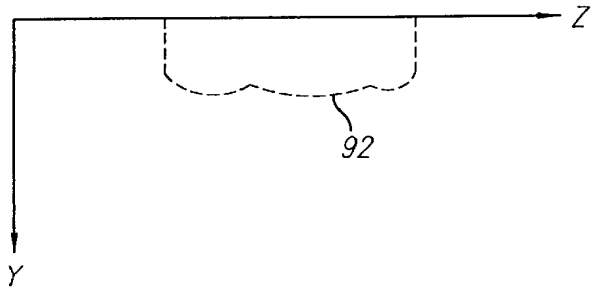


FIG. 10D

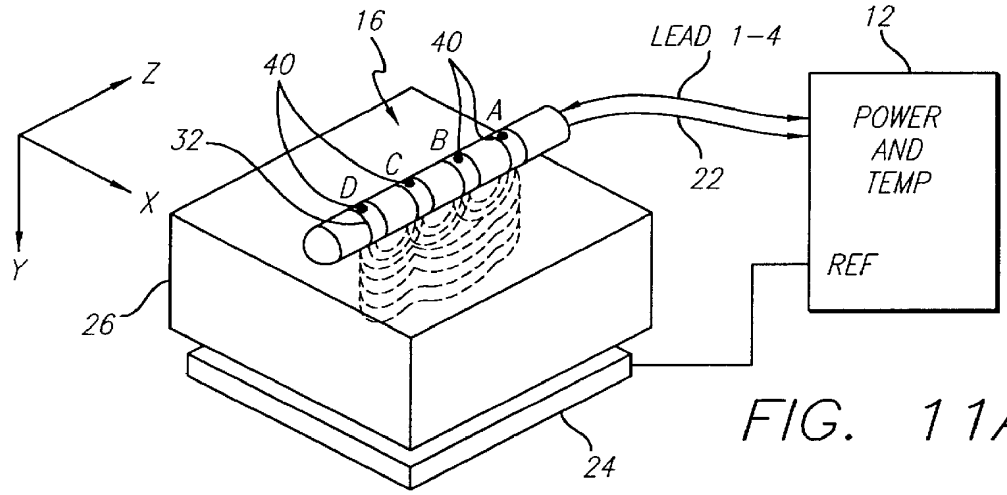


FIG. 11A

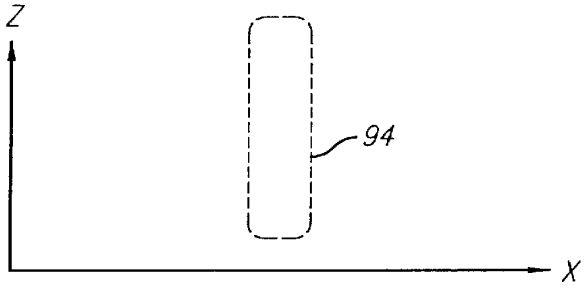


FIG. 11B

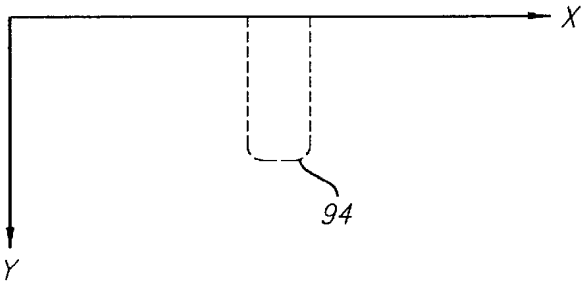


FIG. 11C

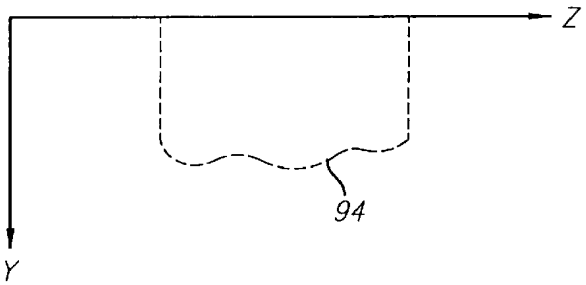


FIG. 11D

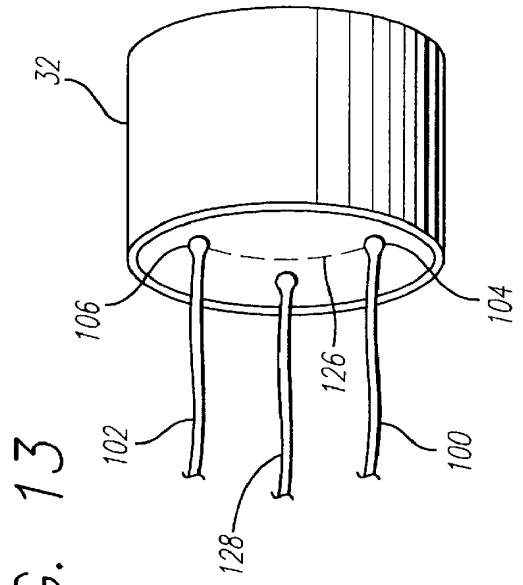


FIG. 13

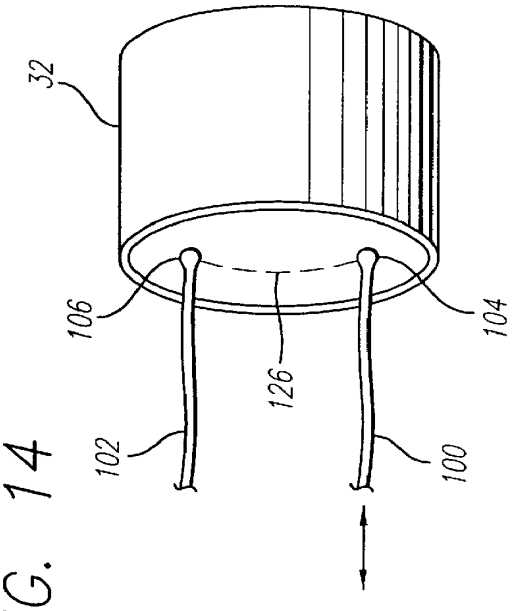


FIG. 14

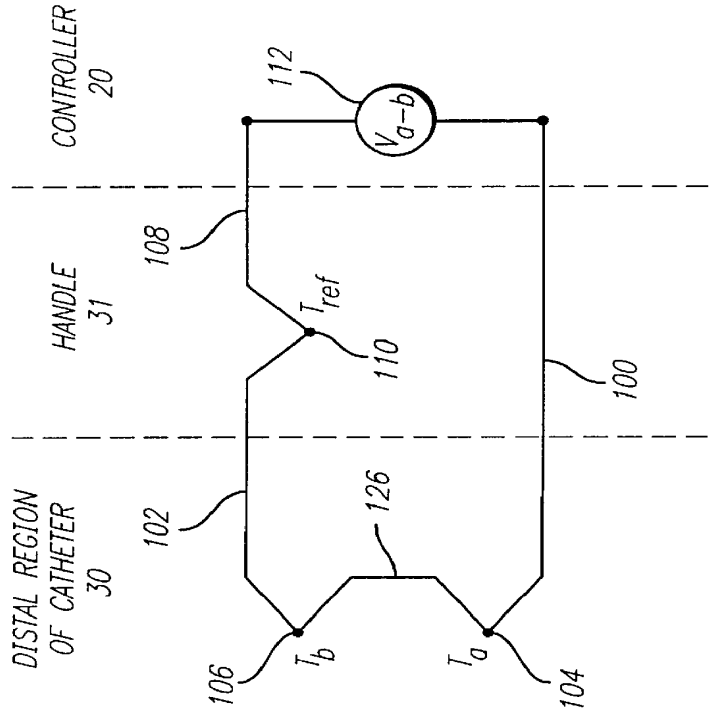


FIG. 12

FIG. 15

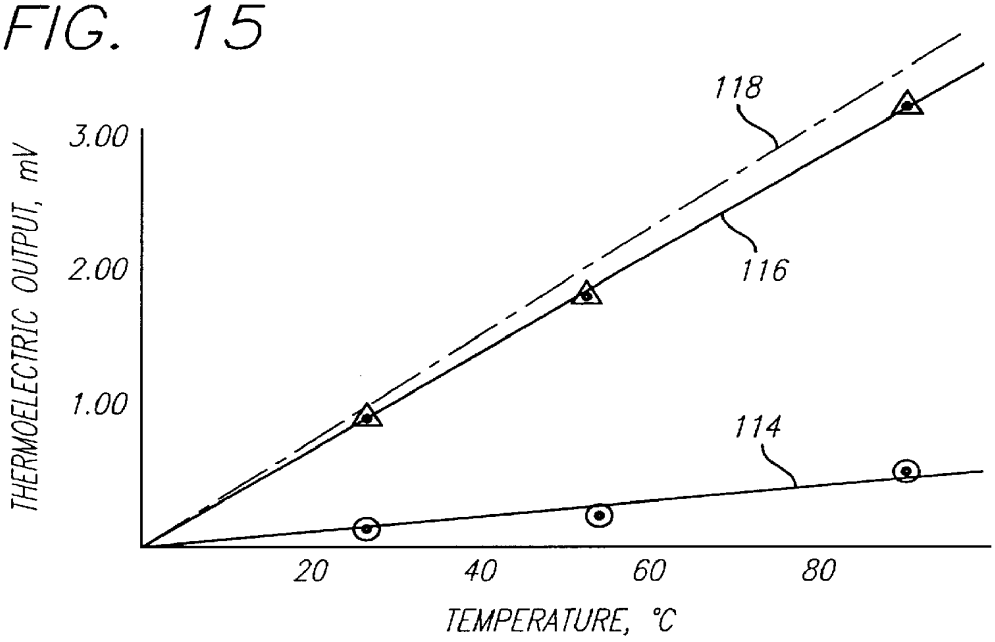

118
116
114
3.00
2.00
1.00
THERMOELECTRIC OUTPUT, mV
20
40
60
80
TEMPERATURE, °C

FIG. 16

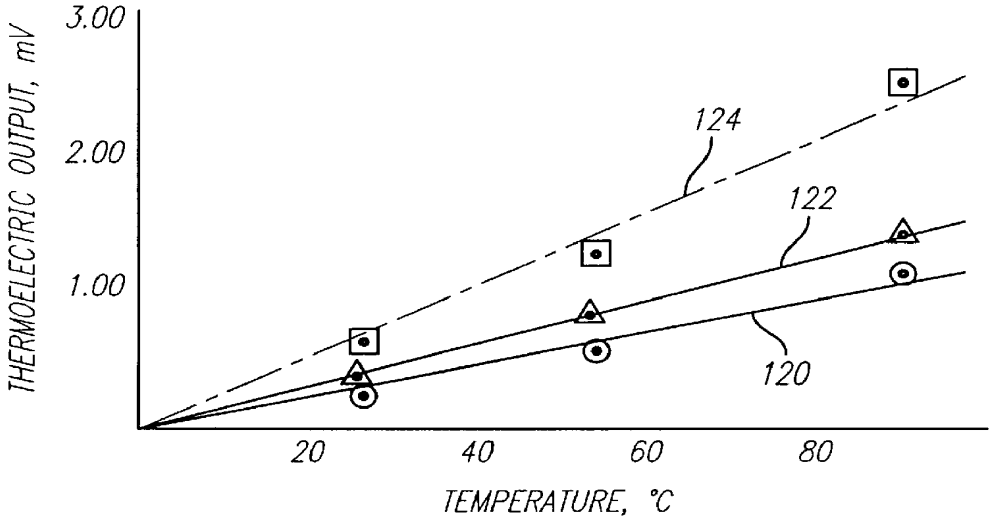
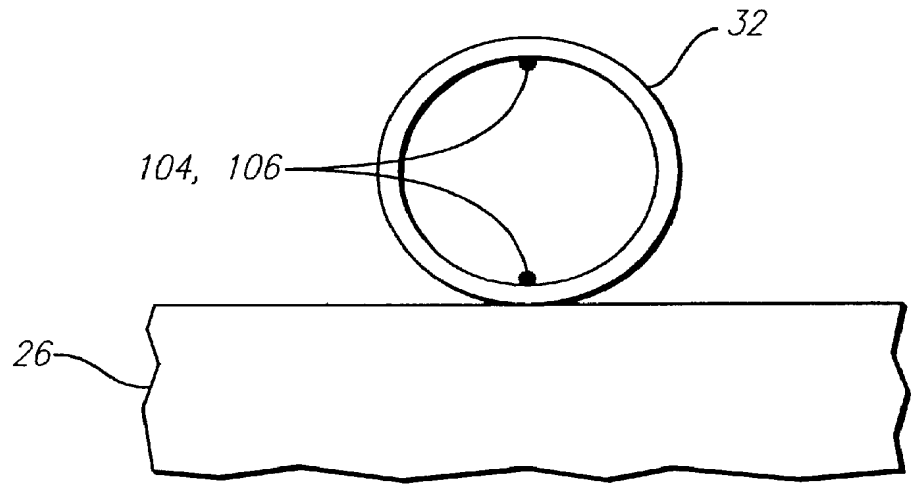

124
122
120
3.00
2.00
1.00
THERMOELECTRIC OUTPUT, mV
20
40
60
80
TEMPERATURE, °C

FIG. 17



ELECTRODE HAVING NON-JOINED THERMOCOUPLE FOR PROVIDING MULTIPLE TEMPERATURE-SENSITIVE JUNCTIONS

BACKGROUND OF THE INVENTION

The invention relates generally to an electrophysiological ("EP") apparatus and method for providing energy to biological tissue, and more particularly, to a catheter having an electrode with a non-joined thermocouple for providing multiple temperature-sensitive junctions on the electrode.

The heart beat in a healthy human is controlled by the sinoatrial node ("S-A node") located in the wall of the right atrium. The S-A node generates electrical signal potentials that are transmitted through pathways of conductive heart tissue in the atrium to the atrioventricular node ("A-V node") which in turn transmits the electrical signals throughout the ventricle by means of the His and Purkinje conductive tissues. Improper growth of, or damage to, the conductive tissue in the heart can interfere with the passage of regular electrical signals from the S-A and A-V nodes. Electrical signal irregularities resulting from such interference can disturb the normal rhythm of the heart and cause an abnormal rhythmic condition referred to as "cardiac arrhythma."

While there are different treatments for cardiac arrhythmia, including the application of anti-arrhythmia drugs, in many cases ablation of the damaged tissue can restore the correct operation of the heart. Such ablation can be performed by percutaneous ablation, a procedure in which a catheter is percutaneously introduced into the patient and directed through an artery to the atrium or ventricle of the heart to perform single or multiple diagnostic, therapeutic, and/or surgical procedures. In such case, an ablation procedure is used to destroy the tissue causing the arrhythmia in an attempt to remove the electrical signal irregularities or create a conductive tissue block to restore normal heart beat or at least an improved heart beat. Successful ablation of the conductive tissue at the arrhythmia initiation site usually terminates the arrhythmia or at least moderates the heart rhythm to acceptable levels. A widely accepted treatment for arrhythmia involves the application of RF energy to the conductive tissue.

In the case of atrial fibrillation ("AF"), a procedure published by Cox et al. and known as the "Maze procedure" involves continuous atrial incisions to prevent atrial reentry and to allow sinus impulses to activate the entire myocardium. While this procedure has been found to be successful, it involves an intensely invasive approach. It is more desirable to accomplish the same result as the Maze procedure by use of a less invasive approach, such as through the use of an appropriate EP catheter system.

There are two general methods of applying RF energy to cardiac tissue, unipolar and bipolar. In the unipolar method a large surface area electrode; e.g., a backplate, is placed on the chest, back or other external location of the patient to serve as a return. The backplate completes an electrical circuit with one or more electrodes that are introduced into the heart, usually via a catheter, and placed in intimate contact with the aberrant conductive tissue. In the bipolar method, electrodes introduced into the heart have different potentials and complete an electrical circuit between themselves. In the bipolar method, the flux traveling between the two electrodes of the catheter enters the tissue to cause ablation.

During ablation, the electrodes are placed in intimate contact with the target endocardial tissue. RF energy is

applied to the electrodes to raise the temperature of the target tissue to a non-viable state. In general, the temperature boundary between viable and non-viable tissue is approximately 48° Centigrade. Tissue heated to a temperature above 48° C. becomes non-viable and defines the ablation volume. The objective is to elevate the tissue temperature, which is generally at 37° C., fairly uniformly to an ablation temperature above 48° C., while keeping both the temperature at the tissue surface and the temperature of the electrode below 100° C.

During ablation, portions of the electrodes are typically in contact with the blood, so that it is possible for clotting and boiling of blood to occur if those electrodes reach an excessive temperature. Both of these conditions are undesirable. Clotting is particularly troublesome at the surface of the catheter electrode because the impedance at the electrode rises to a level where the power delivery is insufficient to effect ablation. The catheter must be removed and cleaned before the procedure can continue. Additionally, too great a rise in impedance can result in sparking and thrombus formation within the heart, both of which are also undesirable.

Further, too great a temperature at the interface between the electrode and the tissue can cause the tissue to reach a high impedance which will attenuate and even block the further transmission of RF energy into the tissue thereby interfering with ablation of tissue at that location.

Even though no significant amount of heat is generated in the electrodes themselves, adjacent heated endocardial tissue heats the electrodes via heat conduction through the tissue. As mentioned above, part of the active electrode will be in contact with the blood in the heart and if the electrode temperature exceeds 90–100°, it can result in blood boiling and clotting on the electrode. The application of RF energy must then be stopped. However, shutting the RF generator off due to the temperature rise may not allow sufficient time to complete the entire ablation procedure. Providing an ablation electrode capable of applying higher amounts of power for a longer period of time to ablate the damaged tissue to an acceptable depth is a goal of current ablation catheter electrode design. It has been found that higher power for longer time periods results in a higher probability of success of the ablation procedure.

To avoid clotting and blood boiling, RF ablation catheters for cardiac applications typically provide temperature feedback during ablation via a temperature sensor such as a thermocouple. In its simplest form, a thermocouple consists of two dissimilar metals joined together at one end called a "bead" or junction, such as a conventional copper/constantan type "T" thermocouple. When the junction is heated a thermoelectric potential arises and can be measured across the unconnected ends. This is also known as the thermoelectric or Seebeck effect. This voltage is proportional to the temperature difference between the junction and the non-joined ends.

A conventional RF ablation catheter typically has a single tip electrode and a single temperature sensor mounted along the centerline of the tip electrode where temperature readings are not affected by the rotational orientation of the catheter. Although a temperature gradient typically exists in tip electrodes, wherein the electrode is hottest at the tissue interface and coolest on the opposite side which is in contact with circulating blood, the centerline sensor provides a moderate output by which it can be determined whether the temperature of the tissue contacted by the electrode is being raised sufficiently, and whether a therapeutic lesion is being generated.

In the case where a catheter has a band electrode, such as for the treatment of atrial fibrillation by the ablation of tissue, a single temperature sensor mounted to the band may not provide the temperature of the tissue contacting the band electrode. Typically the side of the band which is in direct contact with the tissue becomes significantly hotter than the rest of the band electrode that is cooled by the blood flow. Thus, the temperature reading can be dramatically influenced by the rotational orientation of the catheter during RF ablation. If the band is oriented so that the single temperature sensor is not in contact with the tissue during the application of ablation energy, not only would there be a time lag in the sensor reaching the tissue temperature, but due to the effect of the cooling blood flow, the sensor reading may never approach the actual tissue temperature.

To overcome the effect that the rotation orientation of the band electrode has on temperature sensing, two thermocouples, positioned at different locations of the band electrode, may be used. A theory is that having a sensor in contact with tissue is more likely. While attachment of multiple temperature sensors to the band electrode can result in a higher probability of sensing the actual tissue interface temperature, this also increases the number of wires occupying space within the catheter. As is well appreciated by those skilled in the art, an increase in the number of internal wires could mean an undesirable increase in catheter diameter to accommodate those wires. Conventional types of thermocouples each require a thermocouple wire pair. Two thermocouples at each band electrode would result in four wires per band electrode so that the use of multiple temperature sensors may not be practical, particularly where the catheter carries multiple band electrodes that require temperature monitoring.

The larger the catheter, the more traumatic it is to the patient. Also, the more difficult it may be to negotiate the patient's vessels to position the catheter at the desired location in the heart. It is desirable to provide a catheter with as small a diameter as possible. A limiting factor in reducing the size of the catheter is the amount of devices and leads that must be carried inside the catheter. In the case of a catheter having ten band electrodes with two thermocouple temperature sensors at each electrode, a total of fifty wires would be necessary; one power wire for each electrode and two wires for each thermocouple. The size of fifty wires inside a catheter can be significant, causing an increased diameter of the catheter. Yet it is desirable to retain the electrodes and the associated temperature sensors so that more precise control over the energy applied to the biological tissue can be effected. Thus, it would be desirable to reduce the number of wires within a catheter, yet retain the same functionality.

Hence, those skilled in the art have recognized a need for a minimally invasive ablation apparatus that is capable of controlling the flow of current through a biological site so that lesions with controllable surface and depth characteristics may be produced and the ablation volume thereby controlled. Additionally, a need has been recognized for providing an electrode with multiple temperature sensors for providing reliable electrode/tissue interface temperature readings substantially independent of the rotational orientation of the catheter but with a reduced number of sensor leads. Similarly, a need has been recognized for a method for reliably determining the electrode/tissue interface temperature readings substantially independent of the rotational orientation of the catheter but with a reduced number of sensor leads The invention fulfills these needs and others.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the invention is directed to an apparatus and a method for controlling the application of energy to a biological site using a catheter having an energy application device, e. g., an electrode, and a sensor device e. g., a thermocouple, at its distal end for providing multiple temperature-sensitive locations on the electrode with a reduced number of leads.

In a first aspect, an apparatus includes a catheter having an electrode formed of a first metallic material. The electrode is disposed at a distal end of the catheter, the distal end adapted to be positioned so that the electrode is located proximal the biological tissue. The catheter also includes a first electrically conductive member formed of second metallic material, the first member is connected to the electrode at a first junction. Also included is a second electrically conductive member formed of a third metallic material; the second member is connected to the electrode at a second junction. The first, second and third metallic materials are chosen such that when the first and second junctions are at different temperatures a voltage output is produced across the electrode proportional to the temperature difference between the two junctions.

By selecting the first, second, and third metallic materials so that a voltage is produced which is proportional to the temperature average of the two points on the electrode, the present invention allows for the determination of the temperature at two distinct points on the electrode using only one pair of electrically conductive members. Thus the number of wires required to fit within a catheter is reduced, thereby allowing for a reduction in the catheter size.

In a detailed aspect of the invention, the first and second junctions are spaced apart on the electrode such that the voltage output is indicative of a temperature which is the average of the first and second junction temperatures. In a further detailed aspect, the first and second junctions are spaced apart on the electrode such that when the electrode is located proximal the biological tissue, one of the junctions is positioned near the electrode/tissue interface while the other junction is positioned in the biological fluid. In another detailed aspect, the electrode comprises a band electrode and the first and second junctions are located on the band electrode approximately 180 degrees apart around the band electrode inner circumference. In yet another detailed aspect, the second and third metallic materials are metallic materials having Seebeck coefficients relative to the first metallic material that are substantially equal in magnitude but opposite in sign.

In another detailed aspect of the invention, the apparatus further includes a power control system which is adapted to provide power for the electrode and to control the duty cycle of the power with the duty cycle having an on-period and an off-period within a duty cycle time frame. The power control system is further adapted to monitor voltage output produced across the electrode. In a further detailed aspect, the power control system controls the duty cycle of the power in response to the voltage output. In another detailed aspect, the catheter comprises a plurality of electrodes at its distal end, each electrode having a first and second electrically conductive member connected at a first and second junction and the power control system is further adapted to provide power to each of the electrodes wherein the power is selected such that at least two electrodes have voltage levels that differ from each other so that current flows between the two electrodes. In yet more detailed aspects, the power control system provides power with different phase angles to at least two of the electrodes; the power differs in phase by an amount greater than zero degrees but less than 180 degrees; and the power differs in phase by an amount approximately equal to 132 degrees.

In a further detailed aspect, the invention includes a backplate adapted to be positioned proximal the biological site so that the biological site is interposed between the electrodes and the backplate. The power control system is adapted to provide power to the electrodes wherein the power is selected such that at least one electrode has a voltage level that differs from the backplate so that current flows between at least one electrode and the backplate.

In yet another aspect, the invention is an apparatus for delivering energy to biological tissue located in a biological structure in which biological fluids flow past the tissue. The apparatus includes a catheter having a plurality of band electrodes formed of a first metallic material, the band electrodes disposed at a distal end of the catheter, the distal end is adapted to be positioned so that at least one of the band electrodes is located proximal the biological tissue. Also included is a plurality of first electrically conductive members formed of second metallic material, one first member is connected to one band electrode at a first junction. Further included is a plurality of second electrically conductive members formed of a third metallic material, one second member is connected to one band electrode at a second junction. The first, second and third metallic materials are chosen such that when the first and second junctions are at different temperatures a voltage output is produced across the electrode proportional to the temperature difference between the two junctions. Also included is a power control system adapted to provide power to each band electrode and to control the duty cycle of the power with the duty cycle having an on-period and an off-period within a duty cycle time frame. The power control system is further adapted to monitor voltage output produced across each electrode. Still further included is a backplate adapted to be positioned proximal the biological tissue so that the biological tissue is interposed between the electrodes and the backplate.

In a further aspect, a method for monitoring the temperature at the interface between an electrode and biological tissue during ablation of the biological tissue includes the step of positioning a catheter proximal the biological tissue to be ablated. The catheter has an electrode formed of a first metallic material and first and second electrically conductive members connected to the electrode at a first junction and a second junction, respectively. The first and second electrically conductive members are formed of second and third metallic materials, respectively, such that when the two junctions are at different temperatures, a voltage output is produced across the electrode proportional to the temperature average of the two junctions. The first and second electrically conductive members are spaced apart on the electrode. The method further includes the steps of positioning the electrode against the tissue for ablation so that a portion of the electrode is available for contact with the fluids in the biological structure and measuring the voltage output across the electrode as an indication of a temperature which is the average of the two junction temperatures.

In a detailed aspect, the method further includes the steps of placing the first junction in contact with the biological tissue and the second junction in contact with the biological fluid; measuring the temperature of the biological fluid; and determining the temperature of the first junction from the average temperature. In another detailed aspect of the invention, the electrode is a band electrode and the method further comprises the steps of placing the first junction in contact with the biological tissue and the second junction approximately 180° away from the first junction around the band electrode circumference; measuring the temperature of the biological fluid; and determining the temperature of the first junction from the average temperature.

These and other aspects and advantages of the invention will become apparent from the following detailed description and the accompanying drawings, which illustrate by way of example the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic diagram of an ablation apparatus including a power control system, electrode device and backplate;

FIGS. **2-1** and **2-2** form a block diagram presenting more detail of a power control system in accordance with aspects of the invention, showing phase angle control, duty cyde control, and impedance and temperature monitoring;

FIG. **3** is a diagram of a multi-channel ablation apparatus in accordance with aspects of the invention wherein a single microprocessor controls the phase angle and duty cycle of each channel individually;

FIG. **4** depicts a first powerwaveform having a first phase angle and alternating instances of peak power and very low power;

FIG. **5** depicts a second power waveform having a second phase angle different from the first phase angle and alternating instances of peak power and very low power;

FIG. **6** presents a time frame (TF) diagram showing a fifty-percent duty cycle;

FIG. **7**A depicts the phase relationship and voltage potential between the first and second power waveforms having first and second phase angles respectively, as a function of time;

FIG. **7**B depicts the phase relationship and voltage potential between the first and second power waveforms having second and first phase angles respectively, as a function of time;

FIGS. **8**A, **8**B, **8**C, **8**D, and **8**E are schematic diagrams of an embodiment of a power control system in accordance with aspects of the invention with FIG. **8**A showing how FIGS. **8**B, **8**C, **8**D and **8**E are related;

FIG. **9**A is a three dimensional representation of an ablation apparatus having a linear array of band electrodes in contact with a biological site with a backplate at the opposite side of the biological site, in which the phase angle difference between adjacent electrodes of the linear array is zero degrees;

FIGS. **9**B through **9**D depict, along the x, y, and z axes shown, the depth of the lesions formed by the ablation apparatus of FIG. **9**A showing that the apparatus acts as a unipolar device with multiple electrodes and the resulting lesions are discontinuous;

FIG. **10**A is a three dimensional representation of an ablation apparatus having a linear array of band electrodes in contact with a biological site with a backplate at the opposite side of the biological site, in which the phase angle difference between adjacent electrodes is 180 degrees;

FIGS. **10**B through **10**D depict, along the x, y, and z axes shown, the continuity and depth of a lesion formed by the ablation apparatus of FIG. **10**A showing that the apparatus acts as a bipolar device with no significant amount of current flowing to the backplate;

FIG. **11**A is a three dimensional representation of an ablation apparatus having a linear array of band electrodes in contact with a biological site with a backplate at the opposite side of the biological site, in which the phase difference between adjacent electrodes is approximately 90 degrees;

FIGS. **11**B through **11**D depict, along the x, y, and z axes shown, the continuity and depth of a lesion formed by the ablation apparatus of FIG. **11**A showing the greater depth of lesion resulting from the phase angle difference;

FIG. **12** is a schematic diagram of a non-joined thermocouple with thermocouple legs attached to a wire simulating a portion of a band electrode according to the principles of the invention;

FIG. **13** is a diagram of a single band electrode showing the connection of thermocouple wires in accordance with one aspect of the invention where a separate wire conducts ablation energy to the electrode;

FIG. **14** is a diagram of a single band electrode showing the connection of thermocouple wires in accordance with one aspect of the invention where one of the wires also conducts ablation energy to the electrode;

FIG. **15** is a graph showing measured voltage vs. temperature of the thermocouple wire/band electrode/thermocouple wire junctions for a configuration of FIG. **12** having copper and constantan legs, measurements were taken with one junction heated to a target temperature and the other junction held at a fixed temperature of 0° C.;

FIG. **16** is a graph showing measured voltage vs. temperature of the thermocouple wire/band electrode/thermocouple wire junctions for a configuration of FIG. **12** having nickel and molybdenum legs, measurements were taken with one junction heated to a target temperature and the other junction held at a fixed temperature of 0° C.; and

FIG. **17** is a side view of a band electrode having thermocouple legs positioned approximately 180° apart around the circumference of the band electrode in accordance with an aspect of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Turning now to the drawings, in which like reference numerals are used to designate like or corresponding elements among the several figures, in FIG. **1** there is shown an ablation apparatus **10** in accordance with aspects of the present invention. The apparatus **10** includes a power control system **12** that provides power or drive **14** to an electrode device **16**. The power control system **12** comprises a power generator **18** that may have any number of output channels through which it provides the power **14**. The operation of the power generator **18** is controlled by a controller **20** which outputs control signals **21** to the power generator **18**. The controller **20** monitors the power **14** provided by the power generator **18**. In addition, the controller **20** also receives temperature signals **22** from the electrode device **16**. Based on the power **14** and temperature signals **22** the controller **20** adjusts the operation of the power generator **18**. A backplate **24** is located proximal to the biological site **26** opposite the site from the electrode device **16**, and is connected by a backplate wire **28** to the power generator **18**. The backplate **24** is set at the reference level to the power provided to the electrodes, as discussed in detail below.

The electrode device **16** is typically part of a steerable EP catheter **30** capable of being percutaneously introduced into a biological site **26**, e. g., the atrium or ventricle of the heart. The electrode device **16** is shown in schematic form with the components drawn to more clearly illustrate the relationship between the components and the relationship between the components and the power control system **12**. In this embodiment, the catheter **30** comprises a distal segment **34** and a handle **31** located outside the patient. A preferred embodiment of the electrode device **16** includes twelve band electrodes **32** arranged in a substantially linear array along the distal segment **34** of the catheter **30**. The electrode device **16** may include a tip electrode **36**. (For clarity of illustration, only four band electrodes **32** are shown in the figures although as stated, a preferred embodiment may include many more.) The band electrodes **32** are arranged so that there is space **38** between adjacent electrodes. In one configuration of the electrode device **16**, the width of the band electrodes **32** is 3 mm and the space **38** between the electrodes is 4 mm. The total length of the electrode device **16**, as such, is approximately 8 cm.

The arrangement of the band electrodes **32** is not limited to a linear array and may take the form of other patterns. A substantially linear array is preferred for certain therapeutic procedures, such as treatment of atrial fibrillation, in which linear lesions of typically 4 to 8 cm in length are desired. A linear array is more easily carried by the catheter **30** and also lessens the size of the catheter.

The band electrodes **32** are formed of a material having a significantly higher thermal conductivity than that of the biological tissue **26**. Possible materials include silver, copper, gold, chromium, aluminum, molybdenum, tungsten, nickel, platinum, and platinum/10% iridium. Because of the difference in thermal conductivity between the electrodes **32** and the tissue **26**, the electrodes **32** cool off more rapidly in the flowing fluids at the biological site. The power supplied to the electrodes **32** may be adjusted during ablation to allow for the cooling of the electrodes while at the same time allowing for the temperature of the tissue to build up so that ablation results. The electrodes **32** are sized so that the surface area available for contact with fluid in the heart, e. g., blood, is sufficient to allow for efficient heat dissipation from the electrodes to the surrounding blood. In a preferred embodiment, the electrodes **32** are 7 French (2.3 mm in diameter) with a length of 3 mm.

The thickness of the band electrodes **32** also affects the ability of the electrode to draw thermal energy away from the tissue it contacts. In the present embodiment, the electrodes **32** are kept substantially thin so that the electrodes effectively draw energy away from the tissue without having to unduly increase the outer diameter of the electrode. In a preferred embodiment of the invention, the thickness of the band electrodes is 0.05 to 0.13 mm (0.002 to 0.005 inches).

Associated with the electrode device **16** are temperature sensors **40** for monitoring the temperature of the electrode device **16** at various points along its length. In one embodiment, each band electrode **32** has a temperature sensor **40** mounted to it. Each temperature sensor **40** provides a temperature signal **22** to the controller **20** which is indicative of the temperature of the respective band electrode **32** at that sensor. In another embodiment of the electrode device **16** a temperature sensor **40** is mounted on every other band electrode **32**. Thus for a catheter having twelve electrodes, there are temperature sensors on six electrodes. In yet another embodiment of the electrode device **16** every other electrode has two temperature sensors **40**. In FIG. **1**, which shows an embodiment having one temperature sensor for each electrode, there is shown a single power lead **15** for each electrode **32** to provide power to each electrode for ablation purposes and two temperature leads **23** for each temperature sensor **40** to establish the thermocouple effect.

Turning now to FIGS. **2-1** and **2-2**, a block diagram of an ablation apparatus **10** and method in accordance with aspects of the invention is presented. In FIGS. **2-1** and **2-2**, a single channel of the power control system **12** is depicted.

This channel controls the application of power to a single electrode **32**. As will be discussed in relation to other figures, a channel may control a plurality or group of electrodes. In FIG. **2-1**, a microprocessor **42**, which is part of the controller **20** (FIG. **1**), provides a duty cycle control signal **44** to a duty cycle generator **45**. In this case, the duty cycle generator **45** receives the control signal **44** by an 8-bit latch **46**. The latch **46** provides an 8-bit signal **47** to a duty cycle comparator **48**. The comparator **48** compares the 8-bit signal **47** to a count from an 8-bit duty cycle counter **50** and if the count is the same, provides a duty cycle off signal **49** to the duty cycle gate **52**. The gate **52** is connected to a frequency source ("FS") **54**, such as an oscillator that produces 500 kHz. When the gate **52** receives the duty cycle off signal **49** from the comparator **48**, it stops its output of the frequency source signal through the gate and no output exists.

At a frequency of 500 kHz, an 8-bit control has a period or time frame of 0.5 msec. At a fifty-percent duty cycle, the electrode is in the off period only 0.25 msec. To allow for greater cooling of the electrode, the period or time frame **78** (FIG. **6**) is lengthened by use of a prescalar **56** interposed between the frequency source **54** and the counter **50**. In one embodiment, the prescalar **56** lengthens the period to 4 msec thus allowing for a 2 msec off period during a fifty-percent duty cycle. This results in a sufficient cooling time for the very thin band electrodes discussed above. Other lengths of the period may be used depending on the circumstances. It has been found that a ten percent duty cycle is particularly effective in ablating heart tissue. The combination of the application of high peak power, a ten percent duty cycle, the use of high thermal conductivity material in the band electrodes, and fluids flowing past the band electrodes which have a cooling effect on the electrodes result in a much more effective application of power to the tissue. Ablation occurs much more rapidly.

A terminal count detector **58** detects the last count of the period and sends a terminal count signal **59** to the gate **52** which resets the gate for continued output of the frequency source signal. This then begins the on period of the duty cycle and the counter **50** begins its count again. In one preferred embodiment, the duty cycle is set at fifty percent and the 8-bit latch is accordingly set to 128. In another embodiment, the duty cycle is set at ten percent.

A programmable logic array ("PLA") **60** receives phase control signals **61** from the microprocessor **42** and controls the phase of the frequency source **54** accordingly. In one embodiment, the PLA **60** receives the terminal count signal **59** from the terminal count detector **58** and only permits phase changes after receiving that terminal count signal.

The output signal from the gate **52** during the on period of the duty cycle is provided to a binary power amplifier ("BPA") **62** that increases the signal to a higher level, in this case, 24 volts. The amplified signals are then filtered with a band pass filter ("BPF") **64** to convert the somewhat square wave to a sine wave. The band pass filter **64** in one embodiment is centered at 500 kHz. The filtered signal is then provided to an isolated output transformer ("OT") **66** that amplifies the signal to a much higher level, for example 350 volts peak-to-peak. This signal is then sent to a relay interconnect ("RI") **67** before it is provided as a power output signal OUTn **14** to an electrode **32** at the biological site to cause ablation.

The power output signal **14** from the isolated output transformer **66** is monitored in one embodiment to determine the impedance at the electrode **32**. In the embodiment shown in FIGS. **2-1** and **2-2**, a voltage and current monitor ("VCM") **68** is used. The monitor signal **69** is converted to digital form by an A-to-D converter ("ADC") **70** and provided to the microprocessor **42**. As previously mentioned, some or all of the electrodes **32** may include a temperature sensor **40** (FIG. **1**) that provides temperature signals **22** (FIG. **2-2**) which are used to determine the temperature at the electrode **32**. In one embodiment of the invention, the power **14**, in conjunction with the temperature signals **22**, are used to determine the temperature at the electrode **32**. Both the temperature signals **22** and the power **14** pass through a temperature filter ("FL")**73** before being sent to the microprocessor **42**. In the alternative, the temperature filter **73** is contained in a printed circuit board separate from the controller **20** and contains its own processor. In either case, the filter **73** filters out any RF noise present in the power **14** so that the signal may be used for temperature monitoring purposes. In another embodiment, the microprocessor monitors the power **14** and temperature signals **22** only during the off periods of the power **14** duty cycle. Accordingly, negligible RF noise is present in the power line and filtration is not necessary. In either embodiment, the microprocessor **42** may alter the duty cycle of the power **14** in response to either or both of the impedance or temperature signals.

In a manual arrangement, the temperature sensed and/or the determined impedance may be displayed to an operator. The operator in response may then manually control the duty cycle or other power parameters such as by rotating a knob mounted on a front panel of an instrument. In the case of a multiple channel instrument and catheter, as discussed below, multiple knobs may be provided in this manual arrangement for control over each channel.

Referring now to FIG. **3**, a multiple channel ablation apparatus is shown. Although only three complete channels are shown, the apparatus comprises many more as indicated by the successive dots. Those channels are not shown in FIG. **3** to preserve clarity of illustration. By providing different voltage levels between two electrodes **32** in an array, current flows between those electrodes in a bipolar electrode approach. By setting the backplate **24** (FIG. **1**) at a voltage level different from at least one of those electrodes **32**, current flows between that electrode and the backplate. By controlling the voltage levels among the three (two electrodes and backplate), the current flow through the biological site **26** can be more precisely controlled. One technique for setting different voltage levels between the electrodes **32** is to maintain a phase difference between them in an AC approach. By setting the backplate **24** at the reference level, current flows between the electrodes **32** and the backplate.

The single microprocessor **42**, which again is part of the controller **20** (FIG. **1**), controls the duty cycle and the phase of each channel individually in this embodiment. Each channel shown comprises the same elements and each channel produces its own power output signal **14** (OUT**1**, OUT**2**, through OUTn where "n" is the total number of channels) on respective electrode leads (LEAD **1**, LEAD **2**, through LEAD n where "n" is the total number of leads) to the electrodes **32**. This multi-channel approach permits more individual control over each electrode. For example, the duty cycle of the power applied to each electrode can be individually controlled. One electrode may have a ten percent duty cycle while another has a thirty percent duty cycle.

Referring now to the first and second output signals OUT**1** and OUT**2** of FIG. **3**, the signals, as shown in FIGS. **4**, **5**, and **6**, have alternating instances of peak power i. e., "on" periods **74**, and very low power **76**, i. e., "off" periods.

Typically, the output power **14** is a 500 kHz sine wave. In FIGS. **4** and **5**, the number of cycles of the sine wave contained within one on period **74** has been substantially reduced in the drawing to emphasize the phase difference between the first and second output signals OUT1, OUT2. Preferably, the voltage of each power signal **14** during an off period **76** is substantially zero and during an on period **74** is approximately 350 volts peak-to-peak.

The power OUT1 and OUT2 also have a variable duty cycle for controlling the length of the on period **74** and the off-period **76** within a time frame **78** (see FIG. **6**). The duty cycle is the ratio of the length of the on period **74** to the length of the entire time frame **78**. The effective power is the peak power times the duty cycle. Thus, a signal having a peak power of 100 watts and a 50% duty cycle has an effective power of 50 watts.

As shown in FIGS. **4**, **5**, and **6**, the two power signals OUT1, OUT2 are phased differently from each other. As discussed above, the phase angle of each power signal is set and controlled by the processor **42** and PLA **60**. Each power signal OUT1 and OUT2 has a respective phase angle and those phase angles differ between the two of them. The phase angle difference between the power OUT1 and OUT2 produces a voltage potential between the band electrodes **32** (FIG. **1**) that receive the power. This voltage potential, in turn, induces current flow between the band electrodes **32**. The phase angle relationship of the power and the voltage potential produced as a function of time is shown in FIGS. **7**A and **7**B. The potential between electrodes V_{e-e} is defined by:

$$V_{e-e} = 2V\sin\left(\frac{\Delta\Phi}{2}\right)\sin(2\pi ft) \qquad \text{(Eq. 1)}$$

where:

$\Delta\Phi$ = phase angle difference between electrodes

V = voltage amplitude of power

f = frequency in hertz

t = time

FIG. **7**A shows first and second power OUT1 and OUT2 provided to first and second electrodes respectively having a phase angle difference $\Delta\Phi$ with OUT1 leading OUT2 by 132 degrees. FIG. **7**B shows the same power OUT1 and OUT2 but with the phase angles reversed where OUT2 is now leading OUT **1** by 132 degrees.

With reference now to FIGS. **8**A through **8**E, schematic diagrams of an embodiment of the ablation apparatus **10** of FIGS. **2-1** and **2-2** are presented in FIGS. **8**B through **8**E while FIG. **8**A shows how FIGS. **8**B through **8**E should be oriented in relation to each other. The frequency source **54** provides a signal **80**, typically at 500 kHz with a phase angle controlled by the microprocessor **42** through the PLA **60**, to the duty cycle generator **45**. The duty cycle generator **45** modulates the frequency source signal **80** to produce the selected duty cycle in accordance with the duty cycle control signal **44** as previously described. The duty cycle generator **45** outputs two signals **82** and **84** to the binary power amplifier **62**. A dual MOSFET driver U2 receives the signals, converts their 5 V level to a 12 V level, and sends each to a transformer T2 which transforms the signals into 24 V peak-to-peak power.

The 24 V power is then sent to a multi-state driver **86** which includes a configuration of FETs Q2, Q3, Q4, and Q5. During a conducting state of the driver **86**, which is typically the on period **74** of the power, these FETs Q2 through Q5 conduct and forward the power to a bandpass filter **64** comprising a series LC network. During a high-impedance state of the driver **86**, which is typically during the off period **76** of the power, the FETs Q2 through Q5 are nonconducting and no power is sent to the bandpass filter **64**. Instead the FETs Q2 through Q5 present a high impedance load to any signals received through the electrode **32**. Typically the load impedance on the FETs Q2 through Q5 presented by the circuit following the FETs, the electrode, and the tissue is approximately 150 Ω but transformed through the output transformer T3, it presents a load impedance to the FETs Q2–Q5 of approximately 0.5 to 1 Ω. In the off state, the FETs present an impedance of approximately 250 Ω which is large in comparison to the transformed load impedance of approximately 0.5 to 1 Ω. Therefore, very little power flows when the FETs are in the off state.

The bandpass filter **64** operates to shape the output signal provided by the binary amplifier **62** from a square wave to a sinusoidal wave. The filtered signal **85** then passes to the isolated output section **66** where it is step-up transformed to 350 volt peak-to-peak sinusoidal power at T3. The power is then split into two identical power signals OUT1A, OUT1B and provided to two or more respective band electrodes **32** on the output lines LEAD1A, LEAD1B.

The isolated output section **66** also includes relays **88** that may be individually opened to remove the power signals OUT1A, OUT1B from the electrode leads LEAD **1**A, LEAD **1**B when an alert condition is detected, such as high temperature or high impedance at the respective electrode **32**. As previously mentioned these conditions are determined by the microprocessor **42** which receives signals indicative of the temperature and impedance at each of the band electrodes **32**.

The power from the isolated output section **66** is monitored and representative signals are supplied to an RF voltage and current monitor **68** where in this case, the voltage and current of each output signal are measured to determine the impedance of the particular channel. The measured signals are sent to an A-to-D converter **70** (FIG. **2-2**) before being sent to the microprocessor **42** for impedance monitoring. If the impedance is above a threshold level indicative of blood clotting or boiling, the microprocessor **42** sends a signal to the duty cycle generator **45** to reduce or discontinue the duty cycle of the power OUT1A, OUT1B and thus lower the effective power delivered to the band electrodes **32**.

Similarly, the temperature at the electrodes **32** is determined by monitoring the power **14** and temperature signals **22** and measuring the voltage difference between the signals. As previously mentioned, in one embodiment of the invention, these signals pass through a filter **73** (FIG. **2-2**) before being sent to the microprocessor **42**. The voltage value is converted to a temperature and if the temperature is above a threshold level the duty cycle of the power **14** is reduced. In the case where a single lead is used to provide a signal which is used to determine the temperature as well as provide power to the electrode **32**, the signal from the lead is received on temperature leads **87**, **89** connected at the output side of the relays **88**.

As shown in FIG. **3**, the duty cycle of each electrode **32** may be individually controlled by the microprocessor **42**. As previously mentioned, based on the temperature at an electrode **32** and the current and voltage of the output signal provided to an electrode, the duty cycle of the output signal maybe adjusted. For example, one electrode **32** may have a

temperature requiring a duty cycle of ten percent, while another electrode may have a temperature which allows for a fifty percent duty cycle. In an embodiment in which every other electrode **32** has a temperature sensor **40**, the electrodes are grouped in pairs with each electrode in the pair having the same duty cycle.

In operation, as depicted in FIGS. **9**A through **11**D, the electrode device **16** and the backplate **24** are positioned proximal the biological site **26** undergoing ablation such that the biological site is interposed between the electrode device and the backplate. The band electrodes **32** (only one of which is indicated by a numeral **32** for clarity of illustration) of the electrode device **16** each receives power OUT**1**, OUT**2**, OUT**3**, OUT**4** having a phase angle on LEAD **1** through LEAD **4**. In one embodiment, every other electrode **32** receives the same phase angle. Therefore, the phase angle of electrode A equals the phase angle of electrode C and the phase angle of electrode B equals the phase angle of electrode D. The advantages of this arrangement are described below. In a preferred embodiment, the electrodes **32** are formed into a linear array as shown. In addition, a thermocouple temperature sensor **40** is located at each of the electrodes A, B, C, and D and uses the electrode power lead LEADS **1** through **4** as one of the sensor leads. The sensors **40** provide temperature sensor signals **22** for receipt by the power control system **12**.

In another embodiment, alternate electrodes **32** may be grouped together and each may receive the same power having the same phase angle and duty cycle. Another group or groups of electrodes **32** may be interspaced with the first group such that the electrodes of one group alternate with the electrodes of the other group or groups. Each electrode **32** in a particular group of electrodes has the same phase angle and duty cycle. For example, electrodes A and C may be connected to the same power while interspaced electrodes B and D may be connected to a different power output signal.

The use of individual power signals also provides the ability to disable any combination of electrodes **32** and thereby effectively change the length of the electrode device **16**. For example, in one configuration of the present invention an electrode device **16** with twelve electrodes **32** receives twelve power signals from a twelve channel power control system **12**. The electrodes **32** are 3 mm in length and are 4 mm apart. Accordingly, by disabling various electrodes, a virtual electrode of any length from 3 mm to 8 cm may be produced by the electrode device **16**. In either arrangement the backplate **24** is maintained at the reference voltage level in regard to the voltage level of the power OUT**1** through OUTn.

As previously described, by varying the phase angles between the power OUT**1**, OUT**2** supplied to each electrode **32**, a phase angle difference is established between adjacent band electrodes. This phase angle difference may be adjusted to control the voltage potential between adjacent band electrodes **32** and thus to control the flow of current through the biological site **26**. The flow of current $I_{e\text{-}e}$ between adjacent band electrodes **32** is defined by:

$$I_{e-e} = \frac{2V\sin\left(\frac{\Delta\Phi}{2}\right)\sin(2\pi ft)}{Z_{e-e}} \qquad \text{(Eq. 2)}$$

where:

-continued

$\Delta\Phi$ = phase angle difference between electrodes
V = voltage amplitude of power
Z_{e-e} = impedance between electrodes
f = frequency in hertz
t = time

In addition to the current flow between the band electrodes **32** there is current flow between the band electrodes and the backplate **24**. When the backplate **24** is set at the reference level, this current flow $I_{e\text{-}b}$ is defined by:

$$I_{e-b} = \frac{V\sin(2\pi ft)}{Z_{e-b}} \qquad \text{(Eq. 3)}$$

where:

$\Delta\Phi$ = phase angle difference between electrodes
V = voltage amplitude of power
Z_{e-b} = impedance between electrode and backplate
f = frequency in hertz
t = time

Assuming $Z_{e\text{-}b}$ and $Z_{e\text{-}e}$ are equal, the ratio of the current flowing between the band electrodes **32** $I_{e\text{-}e}$ to the current flowing between the band electrodes **32** and the backplate **24** $I_{e\text{-}b}$ is defined by:

$$\frac{I_{e-e}}{I_{e-b}} = 2\sin\left(\frac{\Delta\Phi}{2}\right) \qquad \text{(Eq. 4)}$$

where: $\Delta\Phi$=phase angle difference between electrodes

FIGS. **9**A through **11**D illustrate various current flow patterns within a biological site. The depths and widths of the lesions depicted in FIGS. **9** through **11** are not necessarily to scale or in scalar proportion to each other but are provided for clarity in discerning the differences between the various power application techniques. When the phase difference between adjacent electrodes **32** is zero degrees, no current flows between the electrodes in accordance with Eq. 2 above, and the apparatus operates in a unipolar fashion with the current flowing to the backplate **24** as shown in FIGS. **9**A through **9**D. Substantially all current flows from the band electrodes **32** to the backplate **24** forming a series of relatively deep, acute lesions **90** along the length of the electrode device **16**. As seen in the top view of FIG. **9**B and the side view of FIG. **9**D, the lesions are discrete. The lesions **90** are discontinuous in regard to each other.

When the phase difference between adjacent electrodes **32** is 180 degrees the apparatus operates in both a unipolar and bipolar fashion and the current flow pattern is as shown in FIG. **10**A. With this phase difference, approximately twice as much current flows between adjacent band electrodes **32** than flows from the band electrodes to the backplate **24**. The resulting lesion **92** is shallow but is continuous along the length of the electrode device **16**. The continuity and shallow depth of the lesion **92** are illustrated in FIGS. **10**B through **10**D. Nevertheless, the lesion depth is still greater than that created by prior bipolar ablation methods alone.

When the phase difference between adjacent electrodes **32** is set within the range of a value greater than zero to less than 180 degrees, the current flow varies from a deep, discontinuous unipolar pattern to a more continuous, shallow bipolar pattern. For example, when the phase difference

between adjacent electrodes **32** is around 90 degrees, the current flows as shown in FIG. **11**A. With this phase difference, current flows between adjacent band electrodes **32** as well as between the band electrodes and the backplate **24**. Accordingly, a lesion which is both deep and continuous along the length of the electrode device **16** is produced. The continuity and depth of the lesion **94** is illustrated in FIGS. **11**B through **11**D. In one embodiment of FIG. **11**A, adjacent electrodes alternated in phase but were provided with power in groups. Electrodes A and C were provided with power at a first phase angle and electrodes B and D were provided with power at a second phase angle, different from the first.

Thus, in accordance with the present invention the phase angle of the power may be adjusted in order to produce a lesion having different depth and continuity characteristics. In selecting the phase angle difference necessary to produce a continuous lesion having the greatest possible depth, other elements of the electrode device **16** are considered. For example, the width of the band electrodes **32** and the spacing between the electrodes are factors in selecting an optimum phase angle. In a preferred embodiment of the present invention, as pointed out above, the width of the band electrodes is 3 mm, the spacing between the electrodes is 4 mm and the electrodes receive power which establish a phase difference of 132 degrees between adjacent electrodes. With this configuration a long continuous lesion having a length of between approximately 3 mm and 8 cm and a depth of 5 mm or greater was produced depending on the number of electrodes energized, the duty cycle employed, and the duration of power application.

In another embodiment of the invention, energy is applied to the biological tissue **26** during the on period of the duty cycle in an alternating unipolar-bipolar manner. During the unipolar mode segment a voltage potential is established between the electrodes **32** and the backplate **24**. Thus current flows through the tissue **26** between the electrodes **32** and the backplate **24**.

During the bipolar mode segment a voltage potential is established between at least two of the electrodes **32** rather than between the electrodes and the backplate **24**. Thus current flows through the tissue **26** between the electrodes **32**. While operating in this mode the voltage difference between the electrodes **32** may be established by providing power with different phase angles to the electrodes as previously mentioned. Alternatively, some of the electrodes **32** may be connected to a reference potential while others are maintained at a different voltage level.

By adjusting the duration of the unipolar and bipolar mode segments within the on period of the duty cycle, the continuity and depth of the lesion produced may be controlled. For example, operating in the unipolar mode for one-fourth of the on period and in the bipolar mode for three-fourths of the on period produces a lesion having a continuity and depth similar to the lesion **94** illustrated in FIGS. **11**B through **11**D.

Referring to FIGS. **8**B through and **8**E, the following devices are shown:

Device	Part No.	Manufacturer
U1	GAL6002B	Lattice
U2	SN75372	numerous
Q1	1RFZ34N	numerous
Q2, Q3, Q4, Q5	1RFZ44N	numerous
Q7, Q8, Q9	MPF6601	numerous

-continued

Device	Part No.	Manufacturer
R3, R5	1Ω	numerous
T1, T4	CMI-4810	Corona Magnetics, Inc.
T2	GFS97-0131-1	GFS Manufacturing
T5	CMI-4809	Corona Magnetics, Inc.

The transformer denoted by "T3" is a 1:12 turns ratio, single turn primary, step up transformer wound on a TDK core PC50EER23Z.

The band electrodes **32** generate a heating pattern in the tissue by transmitting RF power into the tissue. The power supplied to the band electrodes **32** is typically increased in order to increase the ablation volume until either an impedance change is noticed due to the onset of clotting or the temperature limit set for the electrode is reached. When one or both of these conditions exist the effective power delivered to the band electrodes **32** is reduced by reducing the duty cycle of the power in this embodiment.

The band electrodes **32** are designed to heat a volume of tissue to an ablation temperature while at the same time assuring that the peak temperature of the band electrodes is controlled so that clotting does not foul the electrode surface and blood boiling does not occur. To this end, each of the band electrodes **32** is formed from a material having a high thermal conductivity. In one embodiment, that material comprised pure platinum. In addition, the band electrodes **32** are sized so that a large surface area is available for contact with the fluid in the heart for dissipating heat to the fluid around the electrode and thereby cooling the electrode. Also, the thickness of the band electrodes **32** is selected so that the electrodes effectively draw heat energy away from the target tissue for cooling purposes without unduly increasing the outside diameter of the electrode device.

In accordance with the present invention, with reference to FIGS. **12**, **13** and **14**, a first electrically conductive member or "leg" **100** and second electrically conductive member or "leg" **102**, are connected independently to the band electrode **32** at first and second junctions **104**, **106**, respectively which are separated from each other. These two electrically conductive members **100**, **102** form the wires, i. e., or "legs" of a thermocouple pair. Because of the separation between the locations at which the first and second legs are attached to the inside surface of the band electrode, the part **126** of the band electrode **32** between the connection points **104** and **106** becomes part of the thermocouple and, in effect, serves as a large thermocouple bead **126**.

A third conductive member or "leg" **108** is electrically connected to the second leg **102** at a reference junction **110**. A voltmeter **112** is disposed across the first leg **100** and the third leg **108** to measure the voltage developed in the thermocouple. In order to correct for extraneous voltage due to dissimilar metal junctions at the voltmeter terminals, the third leg **108** is preferably made of the same material as the first leg **100**. The reference junction **110** and the leads for use in connection to the voltmeter are located in the handle **109** of the catheter and are therefore outside the patient.

Conductive members **100** and **108** are connected to a voltmeter **112** located within the controller **20** (FIG. **1**). The voltmeter **112** (FIG. **12**) provides voltage readings which are related to the temperatures at the various junctions **104**, **106**, and **110**. If the band electrode is heated uniformly, then the temperature reading provided by the two legs will be correct. However, if the temperature of the band electrode is nonuniform, then the voltage output from the two legs will

depend upon the local temperatures at the two leg/band contact points and upon the Seebeck coefficients for the two junctions (leg material A/band material and leg material B/band material). The resulting voltage output V_{ab} measured by a voltmeter **112** is expressed by the following general equation:

$$V_{ab} = \alpha_{ac}(T_a - T_{ref}) - \alpha_{bc}(T_b - T_{ref}) \quad \text{(Eq. 5)}$$

where:
- α_{ac} = Seebeck coefficient for the first leg 100 material and the band material
- α_{bc} = Seebeck coefficient for the second leg 102 material and the band material
- T_a = temperature at the first leg 100/electrode junction 104
- T_b = temperature at the second leg 102/electrode junction 106
- T_{ref} = temperature at the reference junction 110

T_{ref} and the two Seebeck coefficients, α_{ac} and α_{bc}, are typically known for the system at hand. As mentioned briefly above, the reference junction **110** is a controlled temperature junction which is normally included in order to correct for extraneous voltages due to dissimilar metal junctions at the voltmeter terminals. By being located in the handle, for example, the temperature is known to be room temperature, or approximately 22 degrees C. (72 degrees F.). In addition, the Seebeck coefficients are assumed to be constant over the range of temperatures typically encountered in cardiac ablation.

In the present invention, the materials of the first leg **100** and the second leg **102** are chosen such that their Seebeck coefficients, relative to the band electrode **32** material, are equal in magnitude but opposite in sign ($\alpha_{ac}=-\alpha_{bc}$). For pure platinum band electrodes, the following table provides approximate Seebeck coefficients (averaged over the temperature range of from zero to 100° C.) for a variety of different metals and alloys.

METAL OR ALLOY	SEEBECK COEFFICIENT (mV/C) vs. PURE PLATINUM
Bismuth	−0.0734
Constantan	−0.0351
Nickel	−0.0148
Cobalt	−0.0133
Alumel	−0.0129
Mercury	−0.0060
Palladium	−0.0057
Calcium	−0.0051
Gold-chromium	−0.0017
Throium	−0.0013
Platinum	0
Alloy 11	+0.0013
Tantalum	+0.0033
Aluminum	+0.0042
Tin	+0.0042
Lead	+0.0044
Magnesium	+0.0044
Stainless steel, 18-8	+0.0044
Solder 96.5 Sn/3.5 Ag	+0.0045
Solder 50 Sn/50 Pb	+0.0046
Phosphor bronze	+0.0055
Thallium	+0.0058
Yellow brass	+0.0060
Manganin	+0.0061
Iridium	+0.0065
Copper-beryllium	+0.0067
Indium	+0.0069
Rhodium	+0.0070
Silver	+0.0074
Copper	+0.0076
Zinc	+0.0076
Gold	+0.0078
60 Ni/24 Fe/16 Cr	+0.0085
Cadmium	+0.0090
Tungsten	+0.0112
Cerium	+0.0114
80 Ni/20 Cr	+0.0114
Spring steel	+0.0132
Molybdenum	+0.0145
Lithium	+0.0182
Iron	+0.0189
Chromel P	+0.0281
Antimony	+0.0489

From this table, it is apparent that a variety of suitable wire pairs can be selected. In order to increase the voltage output and improve temperature measurement resolution, Seebeck coefficients of large magnitude are preferred.

In one preferred embodiment, the first and second legs **100** and **102** of the thermocouple are pure nickel and pure molybdenum, which have nearly balanced Seebeck coefficients. These legs **100**, **102** are connected to a band electrode **32** of pure platinum.

FIG. **15** shows measured voltage vs. temperature for each thermocouple/band electrode junction when one junction is heated to a target temperature and the other junction is held at a fixed temperature (0° C.). In this thermocouple, the first and second legs **100**, **102** of the thermocouple are pure constantan and pure copper respectively and are connected to a band electrode **32** of pure platinum line **114** represents the thermoelectric output of a copper/platinum junction **104** when heated, while the constantan/platinum junction **106** is maintained at 0° C. in an ice bath. Line **116** represents the thermoelectric output of the constantan/platinum junction **106** when heated, while the copper/platinumjunction **104** is maintained at 0° C. in an ice bath. Line **118** represents the thermoelectric output when both junctions **104** and **106** are heated to the same temperature. The materials chosen for the legs are opposite in sign but are not equal in magnitude. This was done to provide a comparison with a thermocouple configured in accordance with the present invention, as described below and illustrated in FIG. **16**.

FIG. **16** shows measured voltage vs. temperature for each thermocouple/band electrode junction of a preferred embodiment of the invention when one junction is heated to a target temperature and the other junction is held at a fixed temperature (0° C.). In this embodiment the legs **100**, **102** of the thermocouple are pure nickel and pure molybdenum and are connected to a band electrode **32** of pure platinum. Line **120** represents the thermoelectric output of a molybdenum/platinum junction **104** when heated, while the nickel/platinum junction **106** is maintained at 0° C. in an ice bath. Line **122** represents the thermoelectric output of the nickel/platinum junction **106** when heated, while the nickel/platinumjunction **104** is maintained at 0° C. in an ice bath. Line **124** represents the thermoelectric output when both junctions **104** and **106** are heated to the same temperature.

In comparing the graphs of FIGS. **15** and **16**, it is shown that for a given temperature in FIG. **15**, the thermoelectric output is different depending on which junction is experiencing the higher temperature. For example, if the temperature at the electrode/tissue interface is 80° C. and the junction represented by line **114** is in contact with this interface, the voltmeter detects a voltage of approximately

0.5 mV. If, however, the junction represented by line **116** is in contact with this interface, the voltmeter detects a voltage of approximately 2.75 mV. Thus for the same thermal scenario at the electrode/tissue interface the voltmeter readings are different depending on which junction is at the electrode/tissue interface. To accurately determine the temperature at the interface using such a device, it is necessary to know which junction **104, 106** is located at the interface.

The present invention, however, substantially eliminates the dependency on knowing which junction **104, 106** is located at the electrode/tissue interface. This is done by choosing legs **100, 102** which have Seebeck coefficients that are equal in magnitude but opposite in sign. As shown in FIG. **16**, choosing legs **100, 102** as such produces thermoelectric outputs for a given temperature which remain substantially the same regardless of which junction **104, 106** is located at the electrode/tissue interface. Thus the junctions **104, 106** may be transposed without affecting the reliability of the temperature reading.

As indicated in Eq. 5 the thermoelectric output, i.e., voltage output V_{ab}, is related to the two junction temperatures T_a and T_b. Using α_{ab} as the net Seebeck coefficient for the two junctions **104, 106** combined, Eq. 5 reduces to:

$$\begin{aligned} V_{ab} &= \alpha_{ac}[(T_a - T_{ref}) + (T_b - T_{ref})] \\ &= -\alpha_{bc}[(T_a - T_{ref}) + (T_b - T_{ref})] \\ &= (\alpha_{ab}/2)[(T_a - T_{ref}) + (T_b - T_{ref})] \\ &= \alpha_{ab}[(T_a + T_b)/2 - T_{ref}] \end{aligned} \quad \text{(Eq. 6)}$$

Equation 6 shows that the voltage output is related to the average temperature of the two junctions **104, 106**.

During operation of a catheter, depending on the orientation of the band electrode and the positions of the junctions **104, 106** on the band electrode **32**, either one, both, or none of the junctions may be located at the electrode/tissue interface. If the band electrode **32** is positioned such that both junctions **104, 106** are located at the electrode/tissue interface, the temperature reading corresponds to the interface temperature. If, however, neither junction **104, 106** is located at the electrode/tissue interface, the temperature corresponds to the temperature of the blood adjacent to the band electrode **32**. In either of these situations T_a is substantially equal to T_b, i.e., both are the temperature of the electrode/tissue interface or both are the temperature of the local blood pool, and Eq. 6 reduces to:

$$V_{ab}=\alpha_{ab}(T_a-T_{ref})=\alpha_{ab}(T_b-T_{ref}) \quad \text{(Eq. 7)}$$

If the band electrode **32** is positioned such that one junction **104, 106** is located at or near the electrode/tissue interface, while the other junction **104, 106** is located in the local blood pool the resulting temperature reading is the average of the interface and the known blood temperature. Monitoring the blood temperature (T_{blood}) thus permits determination of the temperature of the heated junction T_a or T_b($T_{junction}$) from the average temperature (T_{ave}) using the following equation:

$$T_{junction}=2(T_{ave})-T_{blood} \quad \text{(Eq. 8)}$$

A temperature probe placed in appropriate contact with the patient will provide the blood temperature, which in most cases will be 37 degrees C. (98.6 degrees F.). In principle, this value may be manually input to the controller **20** or input directly to the controller from an actual sensor so that the above calculation may be performed automatically.

In order to determine junction temperature using Eq. 8, it is essential that one of the junctions **104, 106** be located at or near the electrode/tissue interface and the other junction **104, 106** be located in the local blood pool. To this end, the present invention, positions the junctions **104, 106** on the band electrode **32** so that when the electrode is located proximal the biological tissue one of the junctions is positioned at or near the electrode/tissue interface while the other junction is positioned in the biological fluid surrounding the tissue. In a preferred embodiment, the junctions **104, 106** are located on the band electrode approximately 180 degrees apart around the band electrode circumference, as shown in FIG. **17**. The positioning of the junctions in this manner ensures that one of the junctions **104, 106** is located at or near the electrode/tissue contact point substantially independent of the rotational orientation of the catheter. To assist in positioning the electrode **32** at the tissue so that one junction **104, 106** is at the electrode/tissue interface and the other junction is in the surrounding fluid, the distal end of the catheter may be preformed such that a predetermined portion of the catheter surface contacts the biological tissue. This could be done, for example, by preforming the catheter into a curve such that the outer profile of the curve normally lies along the line of tissue contact and orienting one junction on the outer profile and the other junction on the inner profile of the curve. Having the two junctions diametrically opposed, e.g., 180 degrees apart, minimizes the possibility of both junctions contacting the tissue at the same time.

Thus the present invention provides for multiple temperature-sensitive locations, i.e., junctions **104, 106**, on the band electrode **32** using only two thermocouple wires **100, 102**, as opposed to two thermocouple pairs, i.e., four wires, thus resulting in a considerable saving of space in the ablation catheter. This is accomplished by positioning the junctions **104, 106** such that each experiences different temperatures, one being the temperature of the electrode/tissue interface and the other being the temperature of the local blood pool, and by selecting the thermocouple wire material such that either junction **104, 106** may be located at the electrode/tissue interface.

In FIGS. **13** and **14**, a band electrode **32** is shown having a non-joined thermocouple formed at the inside surface of the band from two leads of dissimilar metals **100** and **102**. Each lead **100, 102** is separately connected to the band electrode **32** to form the two junctions **104, 106**. In one embodiment, as shown in FIG. **13**, a separate power lead **128** conducts power to the band electrode **32** to impart ablation energy to the biological target tissue. In another embodiment, as shown in FIG. **14**, the first lead **100** is also used to conduct power to the band electrode **32** to impart ablation energy to the biological target tissue. Thus only two leads **100** and **102** are used to power and sense at the band electrode **32** rather than the three leads as used in other embodiments. This can result in a substantial savings in size because of the existence of one-third fewer leads to be housed by the catheter. In the case of the twelve-band catheter described above in conjunction with FIG. **1**, instead of the normal thirty six leads required, only twenty four leads would be required should the invention be employed. This is a substantial decrease in the number of internal components for the catheter. The inventor hereby incorporates by reference his pending application No. 09/072,800 entitled "Catheter Having Common Lead for Electrode and Sensor" filed may 5, 1998.

Because the thermocouple voltages are typically on the order of 0.001 mV to 0.10 mV per degree C., the power

signals conducted on one thermocouple lead **100** could interfere with the detection of the thermocouple signals generated by the thermocouple. Filtration could be used to separate the DC thermocouple signals from the drive or power signals. In another approach, the controller **20** monitors the leads **100** and **102** for thermocouple signals only during the off-period **76** of the duty cycle **78**, for example, as shown in FIG. **6**. During this off-period, no power is being applied to the band electrode **32** over the first electrode lead **100** and there is less chance for interference with the thermocouple signals produced by the band electrode **32** and conducted on both leads **100** and **102**. Thus, the temperatures may be measured briefly without electrical interference.

It should be appreciated that the invention may also be applied to ablation catheters employing alternate sources of electrical energy for ablation, such as ultrasound or microwave energy. The invention may also be applied to any system in which monitoring temperature is important and where the position of multiple temperature sensors is critical to the accuracy of the measurements.

It will be apparent from the foregoing that while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A combination energy-delivery device/temperature sensor for applying energy to biological tissue and for providing a signal related to the temperature at the device-tissue interface, said apparatus comprising:

an electrode formed of a first metallic material;

a first electrically conductive member formed of second metallic material, the first member connected to the electrode at a first junction;

a second electrically conductive member formed of a third metallic material, the second member connected to the electrode at a second junction; and

wherein the first, second and third metallic materials are chosen such that when the first and second junctions are at different temperatures a voltage output is produced across the electrode proportional to the temperature difference between the two junctions.

2. The apparatus of claim **1** wherein the first and second junctions are spaced apart on the electrode such that the voltage output is indicative of a temperature which is the average of the first and second junction temperatures.

3. The apparatus of claim **1** wherein the electrode is a band electrode and the first and second junctions are located on the band electrode approximately 180 degrees apart around the band electrode circumference.

4. The apparatus of claim **1** wherein the second and third metallic materials are metallic materials having Seebeck coefficients relative to the first metallic material that are substantially equal in magnitude but opposite in sign.

5. The apparatus of claim **1** wherein the first metallic material is platinum.

6. An apparatus for delivering energy to biological tissue located in a biological structure in which biological fluids flow past the tissue, said apparatus comprising:

a catheter having an electrode formed of a first metallic material, the electrode disposed at a distal end of the catheter, the distal end adapted to be positioned so that the electrode is located proximal the biological tissue;

a first electrically conductive member formed of second metallic material, the first member connected to the electrode at a first junction;

a second electrically conductive member formed of a third metallic material, the second member connected to the electrode at a second junction; and

wherein the first, second and third metallic materials are chosen such that when the first and second junctions are at different temperatures a voltage output is produced across the electrode proportional to the temperature difference between the two junctions.

7. The apparatus of claim **1** wherein the first and second junctions are spaced apart on the electrode such that the voltage output is indicative of a temperature which is the average of the first and second junction temperatures.

8. The apparatus of claim **6** wherein the first and second junctions are spaced apart on the electrode such that when the electrode is located proximal the biological tissue one of the junctions is adapted to be positioned near the electrode/tissue interface while the other junction is adapted to be positioned in the biological fluid.

9. The apparatus of claim **1** wherein the electrode is a band electrode and the first and second junctions are located on the band electrode approximately 180 degrees apart around the band electrode circumference.

10. The apparatus of claim **1** wherein the second and third metallic materials are metallic materials having Seebeck coefficients relative to the first metallic material that are substantially equal in magnitude but opposite in sign.

11. The apparatus of claim **1** wherein the first metallic material is platinum.

12. The apparatus of claim **6** further comprising a power control system providing power to the electrode and controlling the duty cycle of the power with the duty cycle having an on-period and an off-period within a duty cycle time frame, the power control system also monitoring the voltage output produced across the electrode.

13. The apparatus of claim **7** wherein the power control system controls the duty cycle of the power in response to the voltage output.

14. The apparatus of claim **12** wherein:

the catheter comprises a plurality of electrodes at its distal end, each electrode having a first and second electrically conductive member connected at a first and second junction; and

the power control system provides power to each of the electrodes wherein the power is selected such that at least two electrodes have voltage levels that differ from each other so that current flows between the two electrodes.

15. The apparatus of claim **14** wherein the power control system provides power with different phase angles to at least two of the electrodes.

16. The apparatus of claim **15** wherein the power differs in phase by an amount greater than zero degrees but less than 180 degrees.

17. The apparatus of claim **15** wherein the power differs in phase by an amount approximately equal to 132 degrees.

18. The apparatus of claim **15** further comprising a backplate adapted to be positioned proximal the biological site so that the biological site is interposed between the electrodes and the backplate;

wherein the power provided by the power control system is selected such that at least one electrode has a voltage level that differs from the backplate so that current flows between at least one electrode and the backplate.

19. The apparatus of claim **18** wherein the power control system controls the duty cycle of the power in response to the voltage output.

20. An apparatus for delivering energy to biological tissue located in a biological structure in which biological fluids flow past the tissue, said apparatus comprising:

a catheter having a plurality of band electrodes formed of a first metallic material, the band electrodes disposed at a distal end of the catheter, the distal end adapted to be positioned so that at least one of the band electrodes is located proximal the biological tissue;

a plurality of first electrically conductive members formed of second metallic material, for each of the plurality of band electrodes, one first member connected to the electrode at a first junction;

a plurality of second electrically conductive members formed of a third metallic material, for each of the plurality of band electrodes, one second member connected to the electrode at a second junction, wherein the first, second and third metallic materials are chosen such that when the first and second junctions are at different temperatures a voltage output is produced across the electrode proportional to the temperature difference between the two junctions;

a power control system providing power to each band electrode and controlling the duty cycle of the power with the duty cycle having an on-period and an off-period within a duty cycle time frame, the power control system also monitoring the voltage output produced across each electrode; and

a backplate adapted to be positioned proximal the biological tissue so that the biological tissue is interposed between the electrodes and the backplate.

21. The apparatus of claim **20** wherein the first and second junctions are spaced apart on each band electrode such that the voltage output is indicative of a temperature which is the average of the first and second junction temperatures of that band electrode.

22. The apparatus of claim **20** wherein the first and second junctions are spaced apart on each band electrode such that when the band electrode is located proximal the biological tissue one of the junctions is adapted to be positioned near the electrode/tissue interface while the other junction is adapted to be positioned in the biological fluid.

23. The apparatus of claim **20** wherein the first and second junctions are located on the band electrode approximately 180° apart around the band electrode circumference.

24. The apparatus of claim **20** wherein the second and third metallic materials are metallic materials having Seebeck coefficients relative to the first metallic material that are substantially equal in magnitude but opposite in sign.

25. The apparatus of claim **20** wherein the first metallic material is platinum.

26. A method for monitoring the temperature at the interface between an electrode and biological tissue during ablation of the biological tissue, the biological tissue being located in a biological structure in which fluids flow past the tissue to be ablated, said method comprising the steps of:

positioning a catheter proximal the biological tissue to be ablated, the catheter having an electrode formed of a first metallic material and first and second electrically conductive members connected to the electrode at a first junction and a second junction, respectively, the first and second electrically conductive members being formed of second and third metallic materials, respectively, such that when the two junctions are at different temperatures, a voltage output is produced across the electrode proportional to the temperature difference between the two junctions, the first and second electrically conductive members being spaced apart on the electrode;

positioning the electrode against the tissue for ablation so that a portion of the electrode is available for contact with the fluids in the biological structure; and

measuring the voltage output across the electrode as an indication of a temperature which is the average of the two junction temperatures.

27. The method of claim **26** further comprising the steps of:

placing the first junction in contact with the biological tissue and the second junction in contact with the biological fluid;

measuring the temperature of the biological fluid; and

determining the temperature of the first junction from the average temperature.

28. The method of claim **26** wherein the electrode is a band electrode and the method further comprises the steps of:

placing the first junction in contact with the biological tissue and the second junction approximately 180 degrees away from the first junction around the band electrode circumference;

measuring the temperature of the biological fluid; and

determining the temperature of the first junction from the average temperature.

29. The method of claim **26** wherein the second and third metallic materials are metallic materials having Seebeck coefficients relative to the first metallic material that are substantially equal in magnitude but opposite in sign.

30. The method of claim **26** wherein the first metallic material is platinum.

31. A method for designing an electrode device for use during ablation of biological tissue, the biological tissue located in a biological structure in which fluids flow past the tissue to be ablated, the electrode device for providing a voltage output indicative of a temperature which is the average temperature of multiple electrode locations, the designing method comprising the steps of:

forming an electrode of a first metallic material;

connecting a first electrically conductive member formed of a second metallic material to the electrode at a first junction;

connecting a second electrically conductive member formed of a third metallic material to the electrode at a second junction spaced apart from the first junction; and

wherein the second and third metallic materials are metallic materials having Seebeck coefficients relative to the first metallic material that are substantially equal in magnitude but opposite in sign.

32. The method of claim **31** wherein the first and second junctions are spaced apart on the electrode such that when the electrode is located proximal the biological tissue one of the junctions is positioned near the electrode/tissue interface while the other junction is positioned in the biological fluid.

33. The method of claim **31** wherein the electrode is formed as a band electrode and the first and second junctions are located on the band electrode approximately 180 degrees apart around the band electrodes circumference.

34. The method of claim **31** wherein the first metallic material is platinum.

35. A combination energy-delivery device/temperature sensor for applying energy to biological tissue and for measuring the temperature at the device-tissue interface, said apparatus comprising:

an electrode formed of a first metallic material:

a first electrically conductive member formed of second metallic material, the first member connected to the electrode at a first junction;

a second electrically conductive member formed of a third metallic material, the second member connected to the electrode at a second junction;

a voltmeter for determining the voltage across the first electrically conductive member and the second electrically conductive member;

a processor for converting each voltage to a temperature value; and

wherein the first, second and third metallic materials are chosen such that when the first and second junctions are at different temperatures the voltage output produced across the conductive members is proportional to the temperature difference between the two junctions.

36. The apparatus of claim **35** wherein the first and second junctions are spaced apart on the electrode such that the voltage output is indicative of a temperature which is the average of the first and second junction temperatures.

37. The apparatus of claim **35** wherein the electrode is a band electrode and the first and second junctions are located on the band electrode approximately 180 degrees apart around the band electrode circumference.

38. The apparatus of claim **35** wherein the second and third metallic materials are metallic materials having Seebeck coefficients relative to the first metallic material that are substantially equal in magnitude but opposite in sign.

39. The apparatus of claim **35** wherein the first metallic material is platinum.

* * * * *

EXHIBIT 2

US005464395A

United States Patent [19]

Faxon et al.

[11] **Patent Number: 5,464,395**

[45] **Date of Patent: Nov. 7, 1995**

[54] **CATHETER FOR DELIVERING THERAPEUTIC AND/OR DIAGNOSTIC AGENTS TO THE TISSUE SURROUNDING A BODILY PASSAGEWAY**

[76] Inventors: **David P. Faxon**, 2027 Ashbourne Dr., South Pasadena, Calif. 91030; **Christian C. Haudenschild**, 7600 Timbercrest Dr., Rockville, Md. 20855

[21] Appl. No.: **223,451**

[22] Filed: **Apr. 5, 1994**

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **604/96**; 604/164; 604/264

[58] **Field of Search** 604/96, 264, 198, 604/187, 164, 51–55, 165–169; 128/831

[56] **References Cited**

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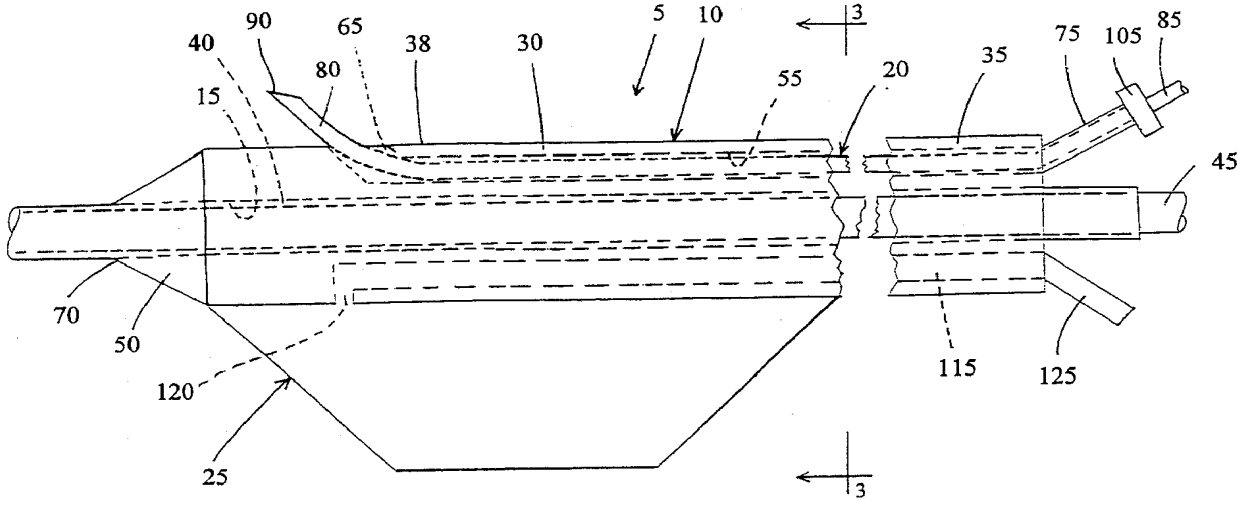
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Pandiscio & Pandiscio

[57] **ABSTRACT**

A catheter for delivering therapeutic and/or diagnostic agents directly into the tissue surrounding a bodily passageway. The catheter comprises at least one needle cannula able to be projected outboard of the catheter so as to deliver the desired agents to the tissue. The catheter also preferrably includes one or more inflatable balloons.

16 Claims, 15 Drawing Sheets



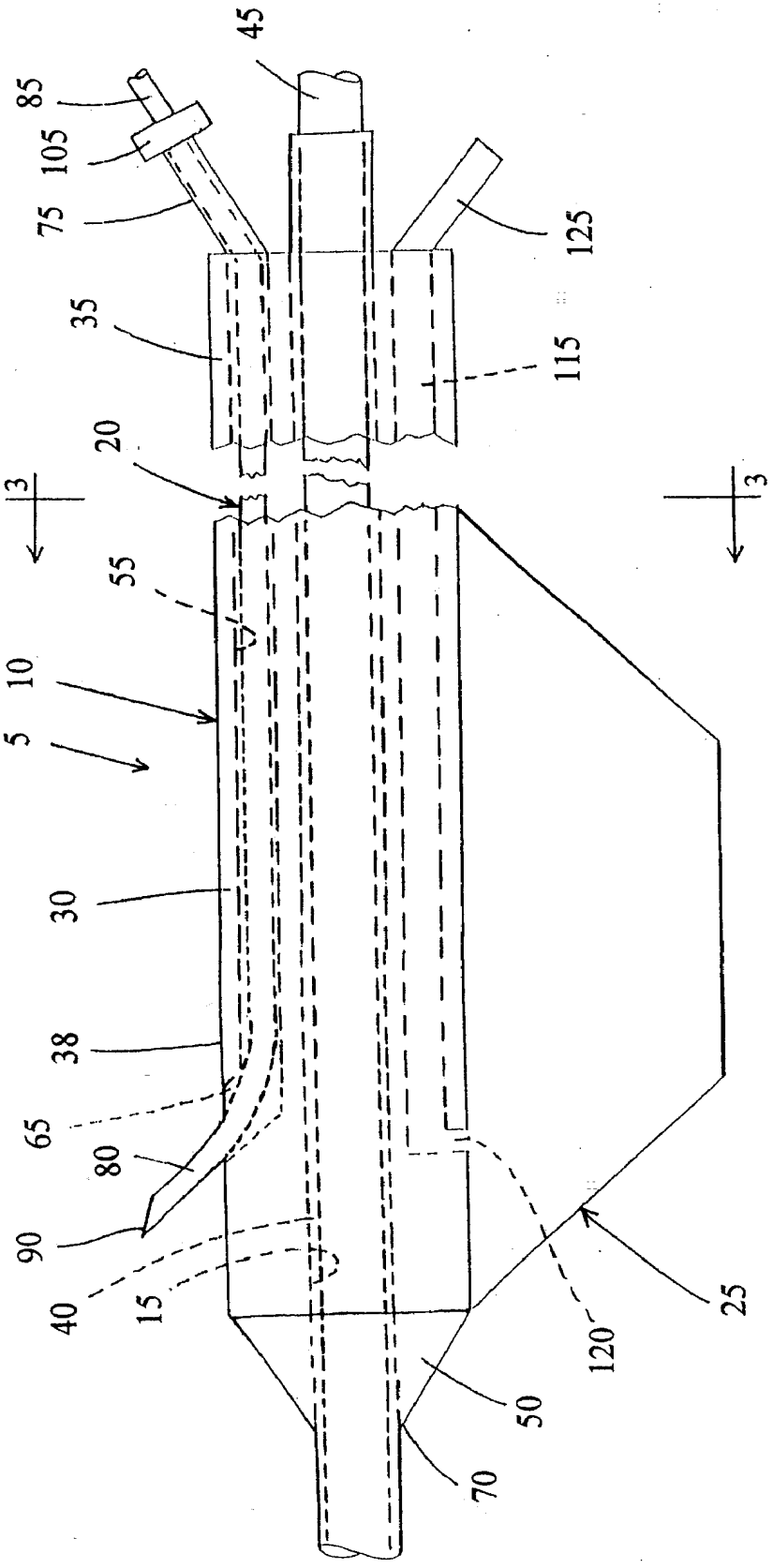


FIG. 1

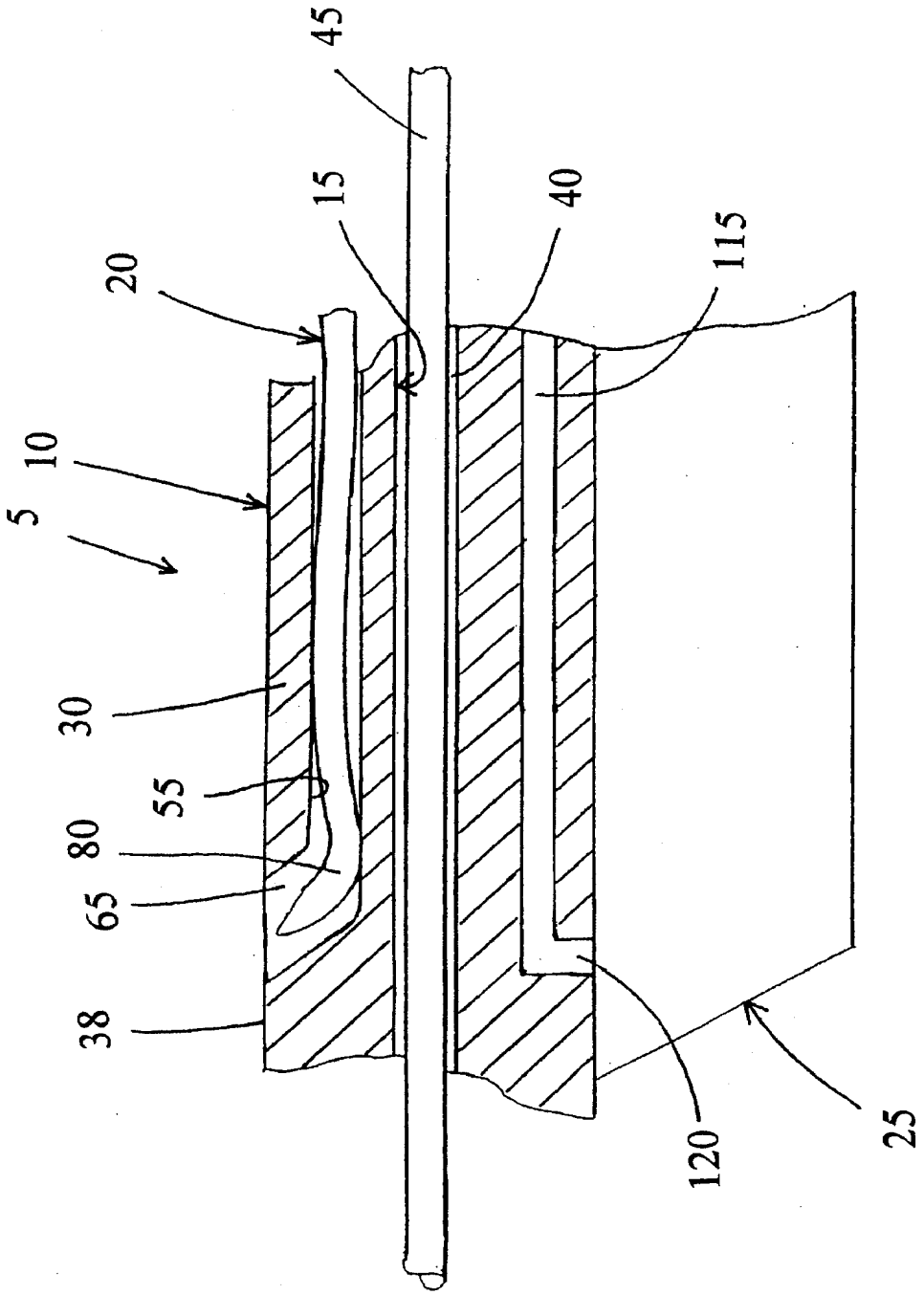


FIG. 2

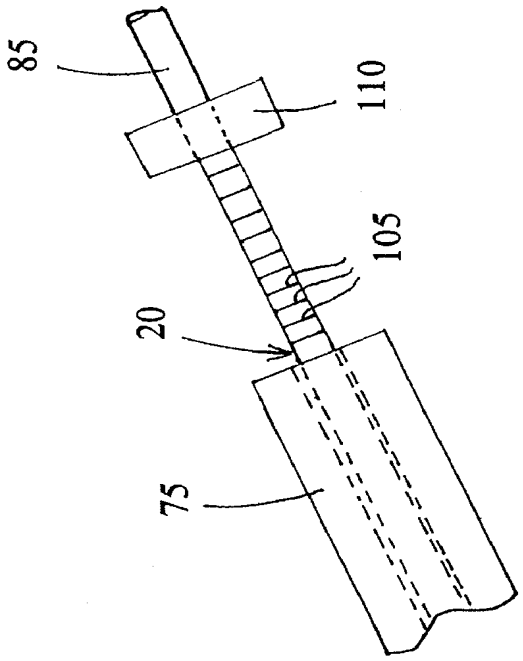


FIG. 4

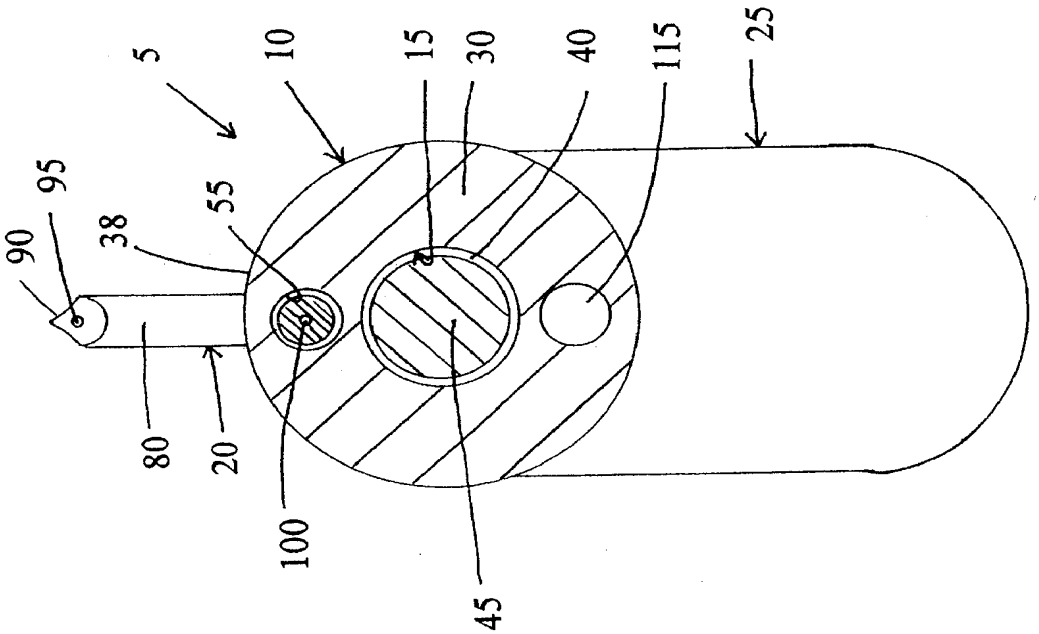


FIG. 3

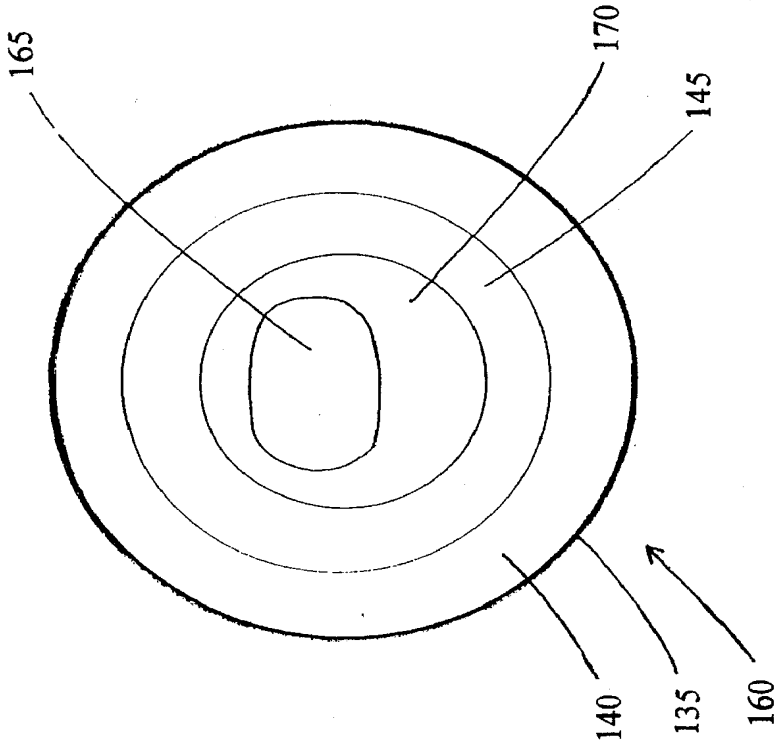


FIG. 6

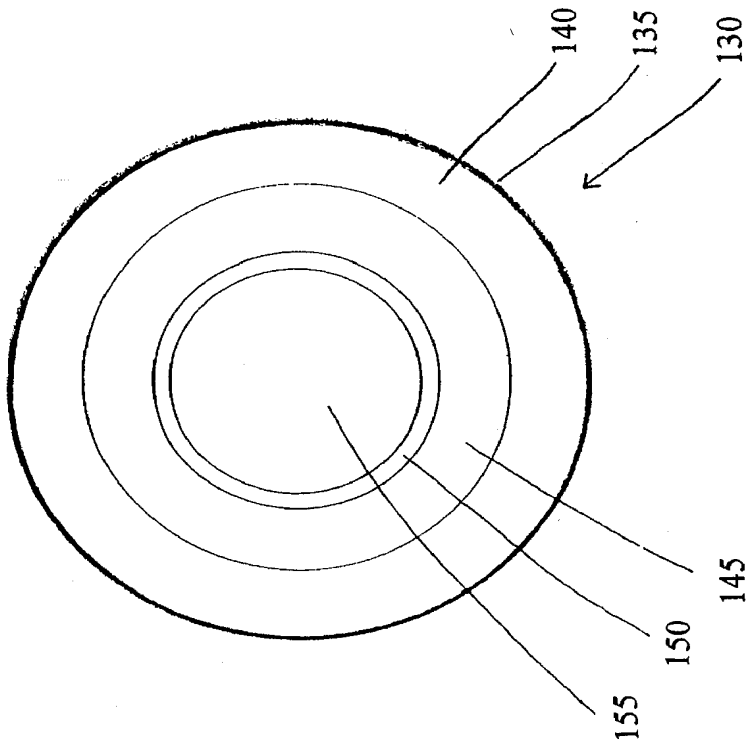


FIG. 5

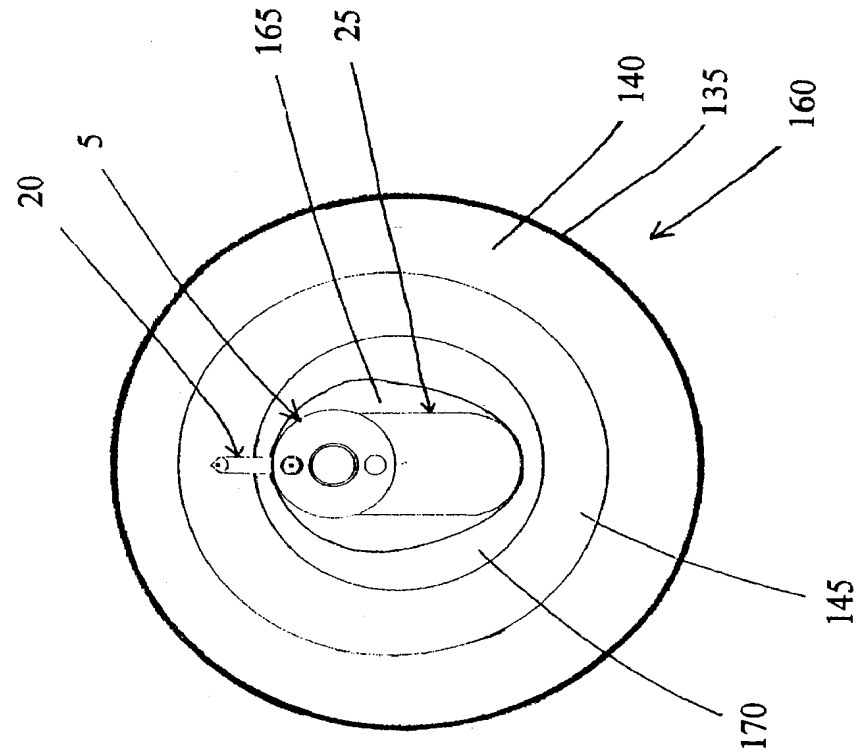


FIG. 8

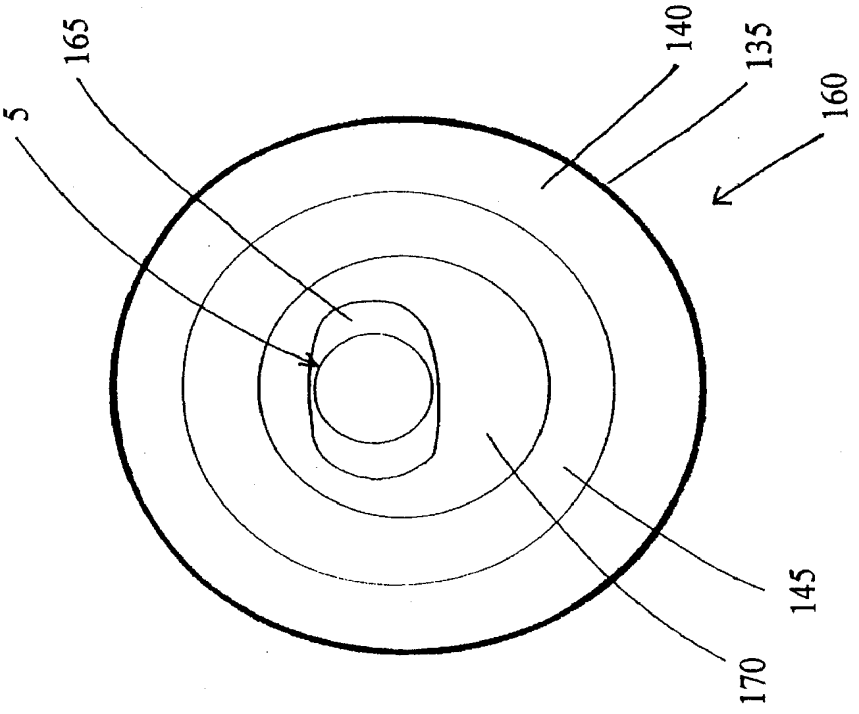


FIG. 7

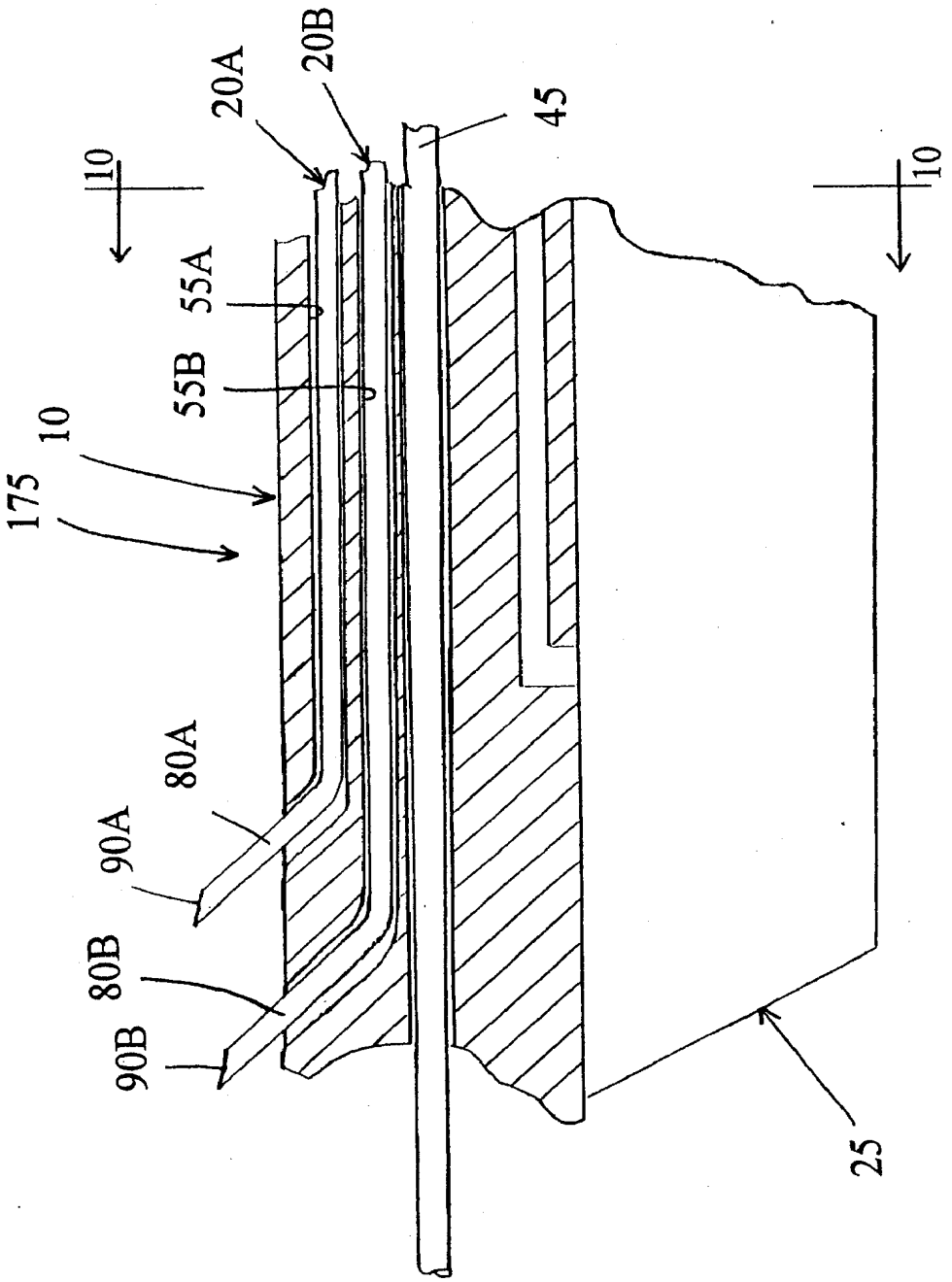


FIG. 9

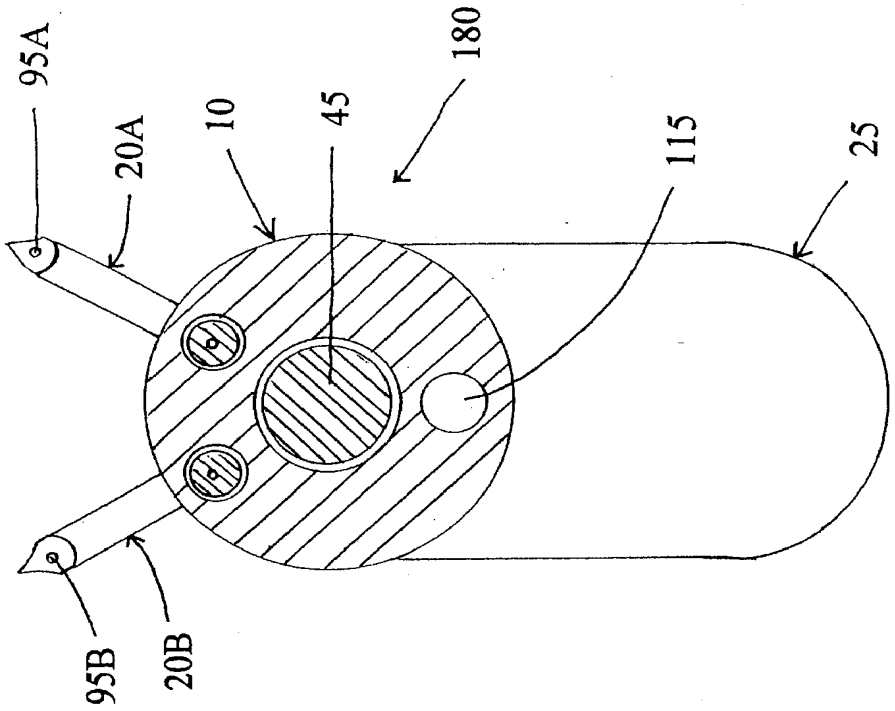

95A
20A
10
45
180
115
25
95B
20B

FIG. 11

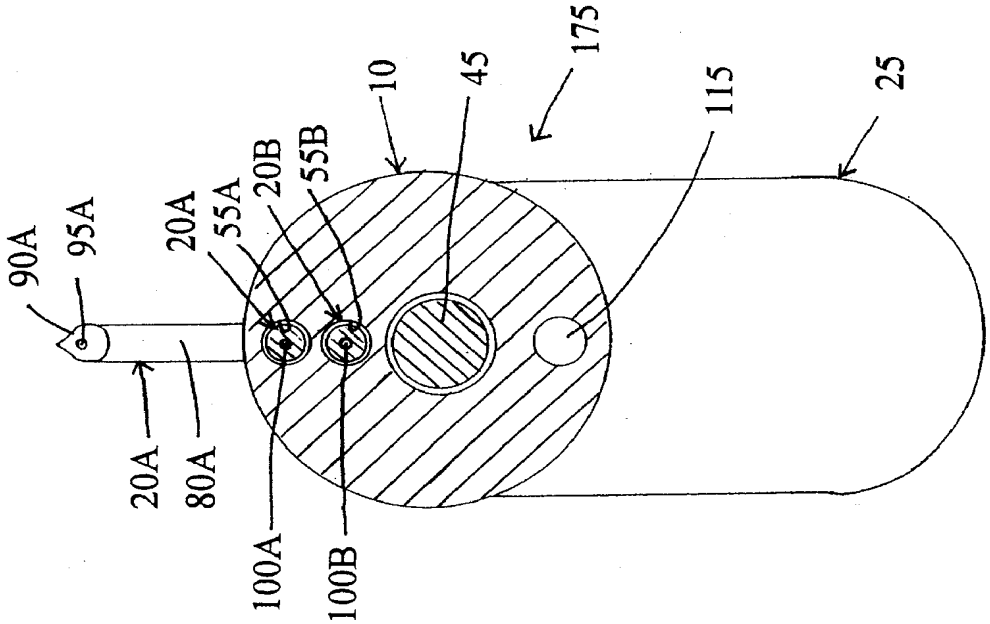

90A
95A
20A
55A
20B
55B
10
45
175
115
25
20A
80A
100A
100B

FIG. 10

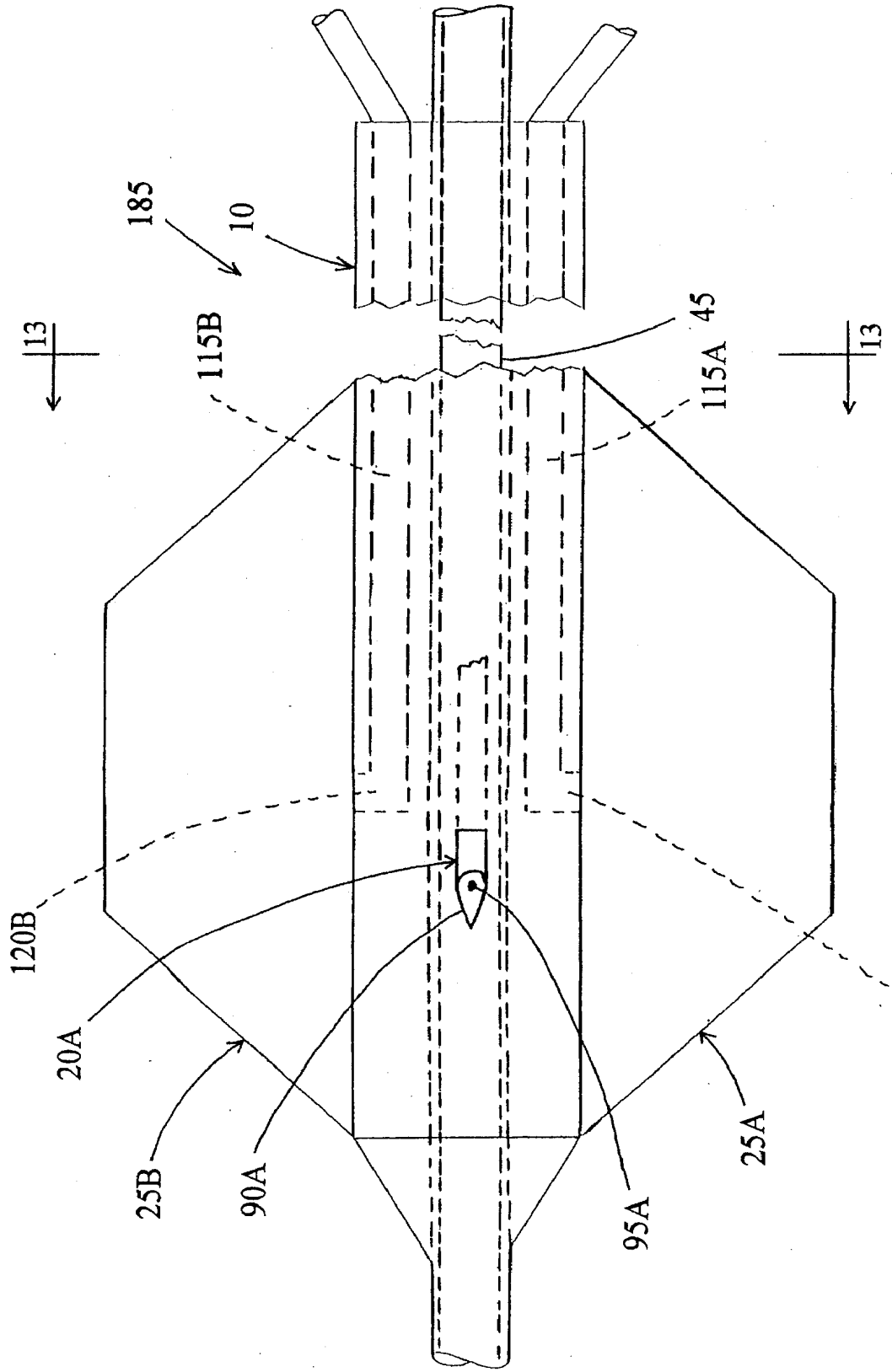


FIG. 12

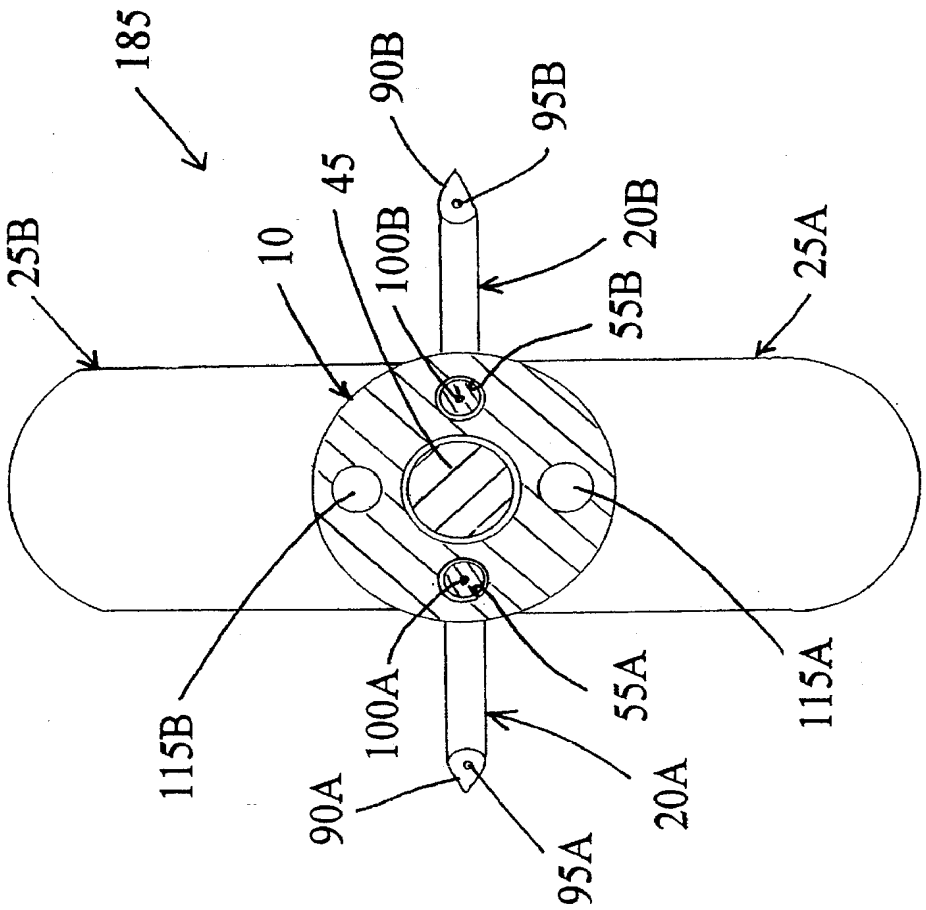

185
90B
95B
45
25B
10
100B
20B
25A
55B
115B
100A
55A
115A
90A
20A
95A

FIG. 13

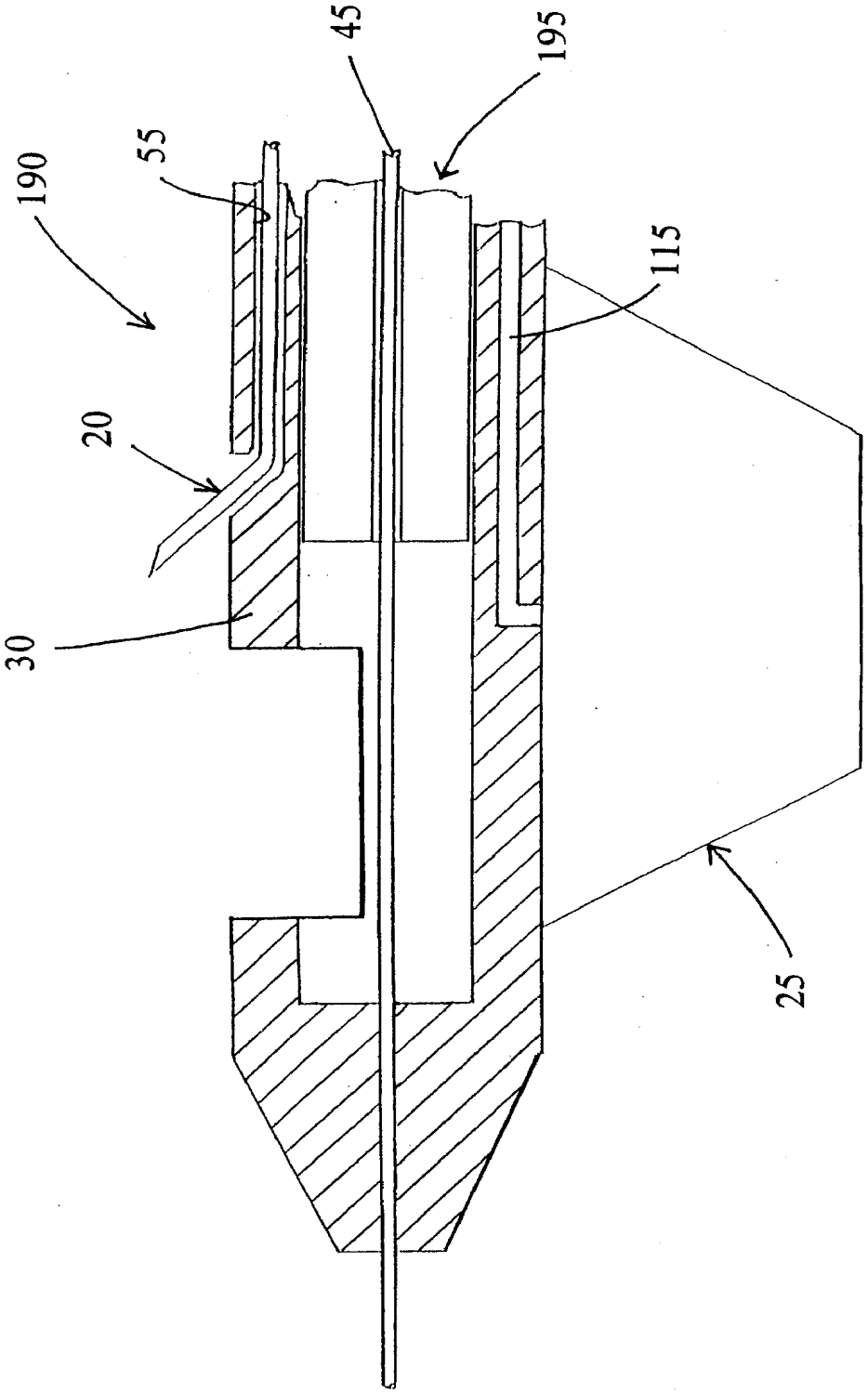


FIG. 14

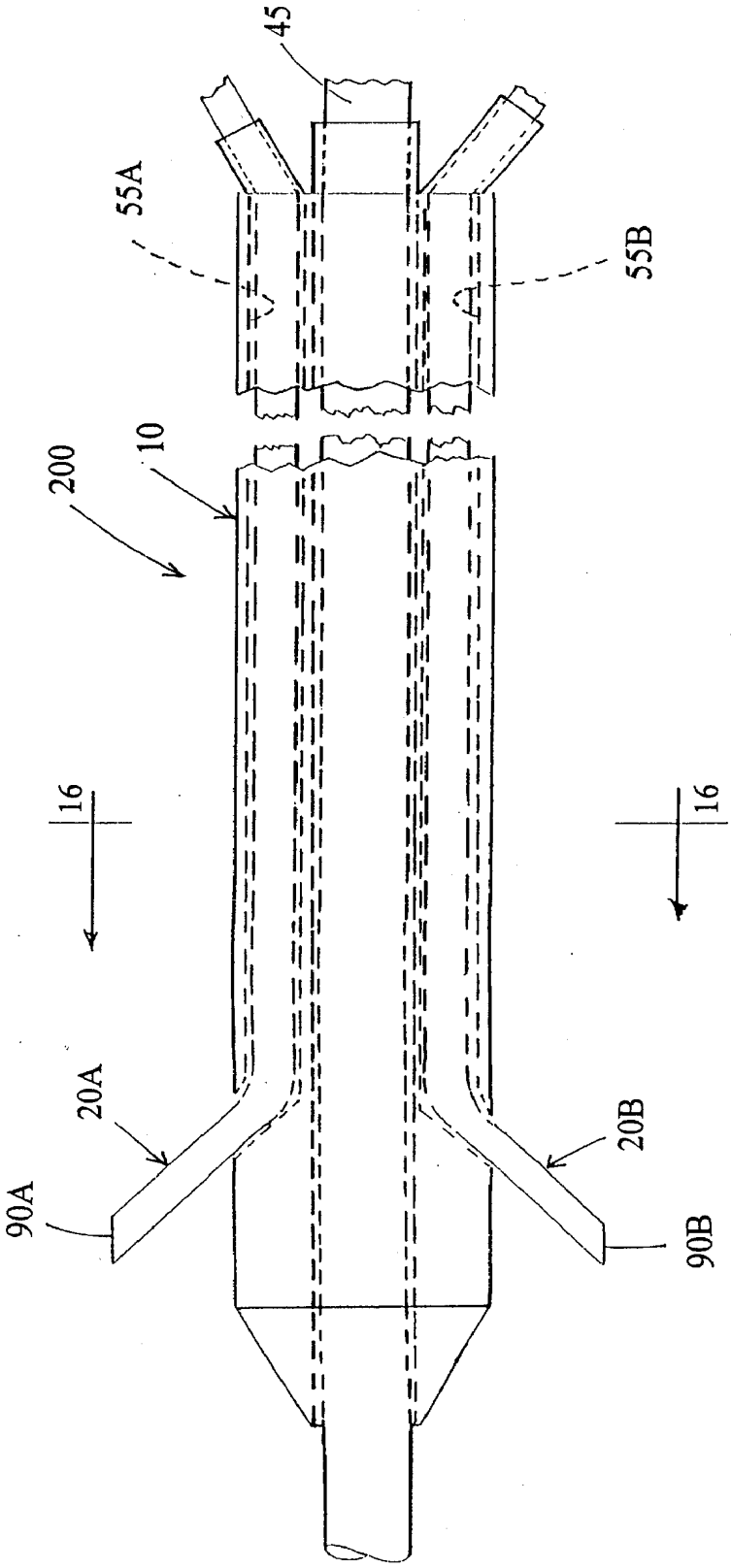


FIG. 15

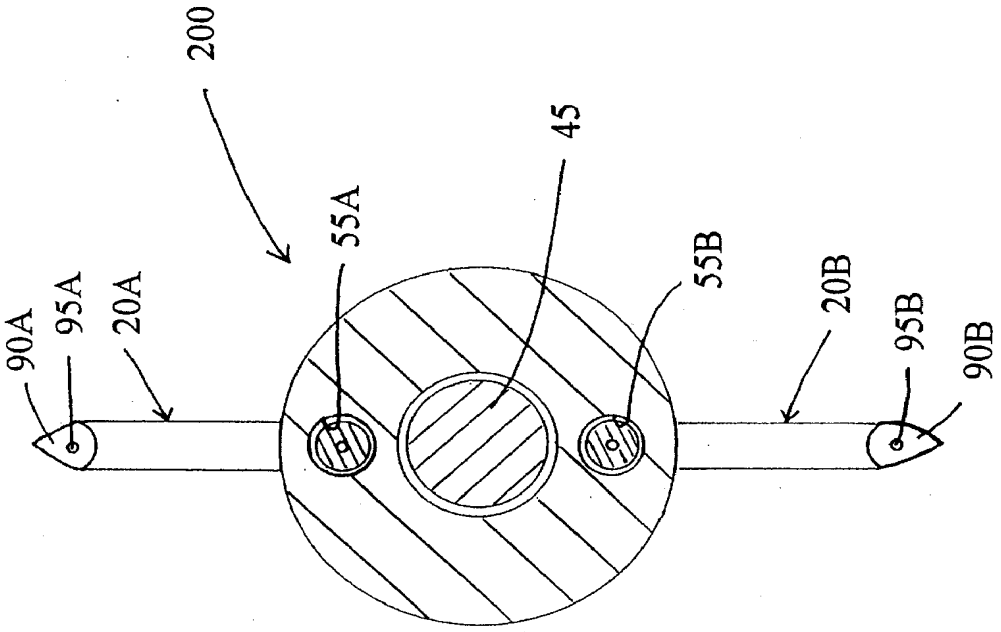


FIG. 16

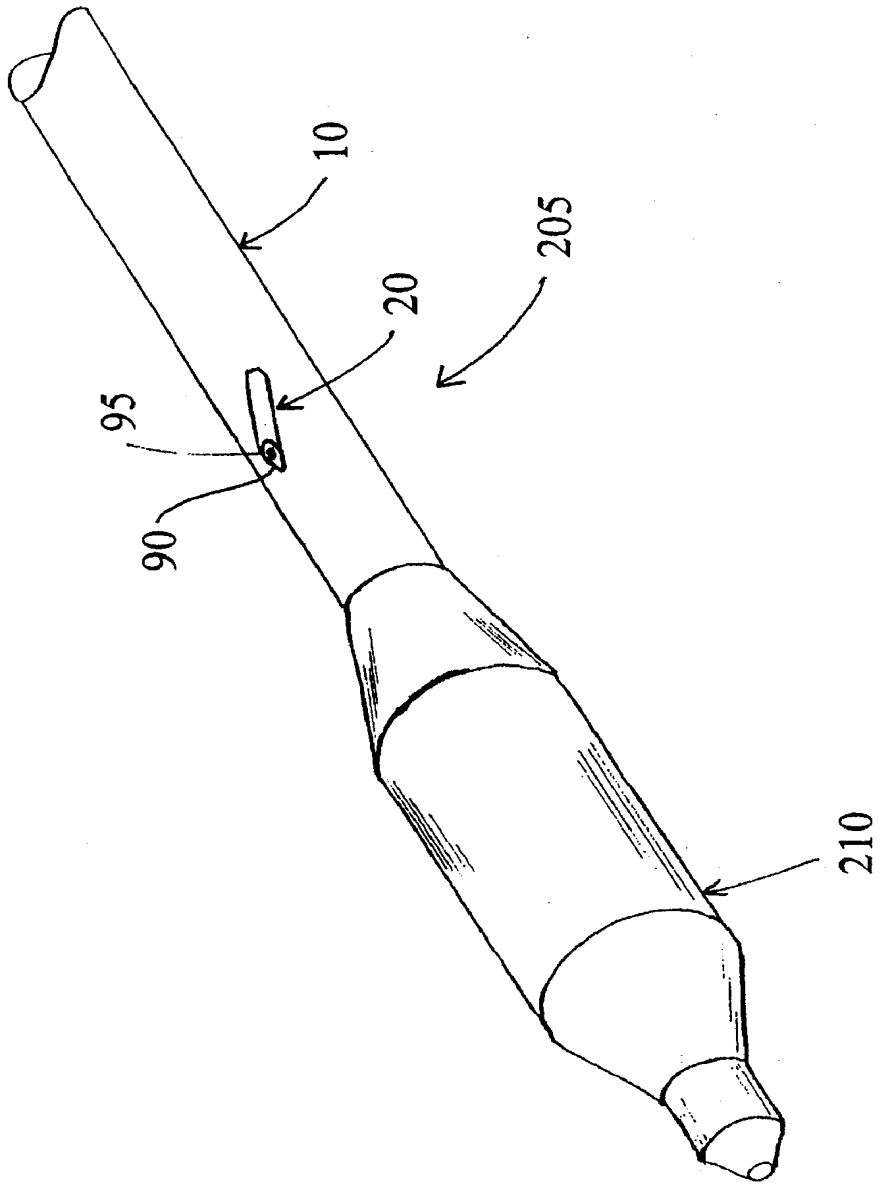


FIG. 17

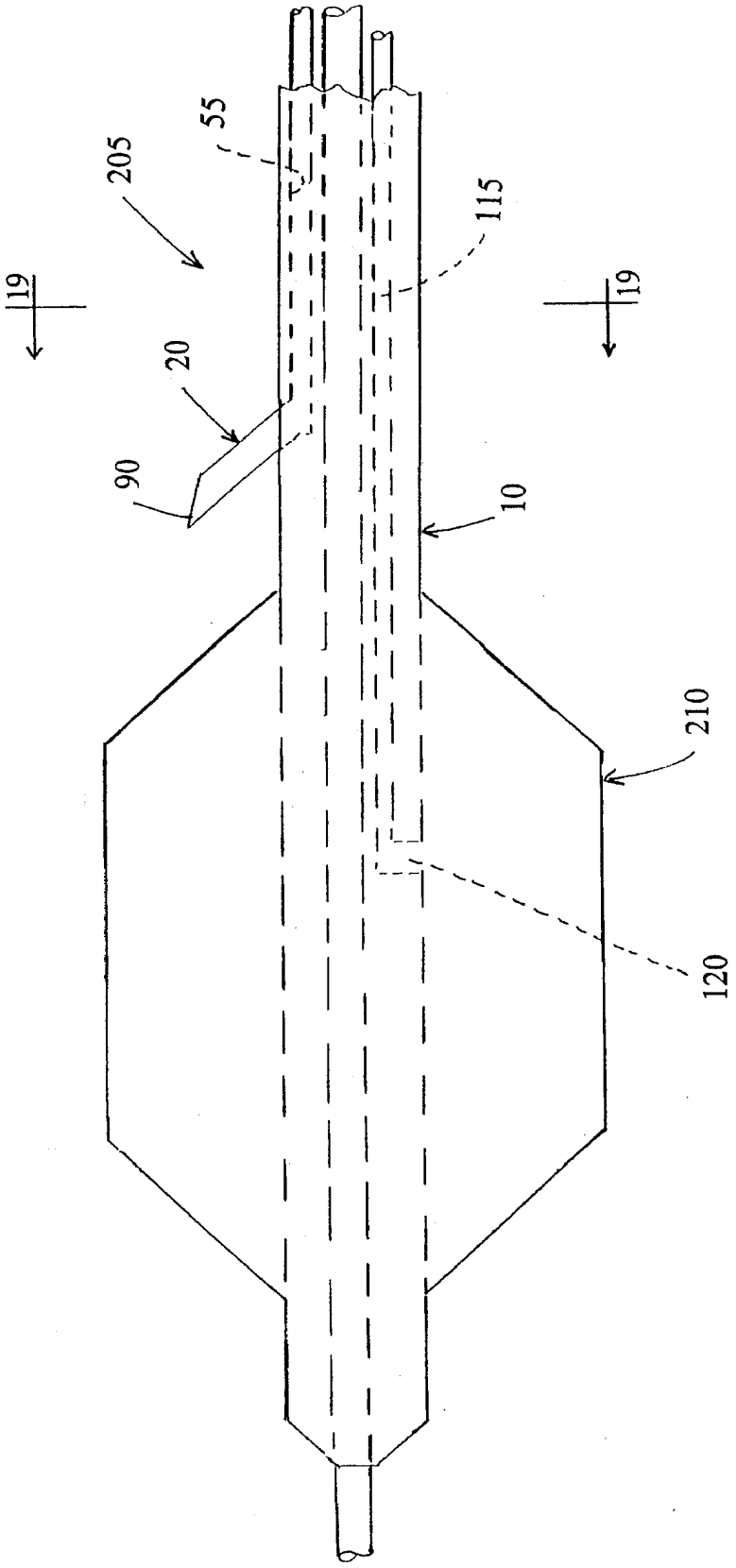


FIG. 18

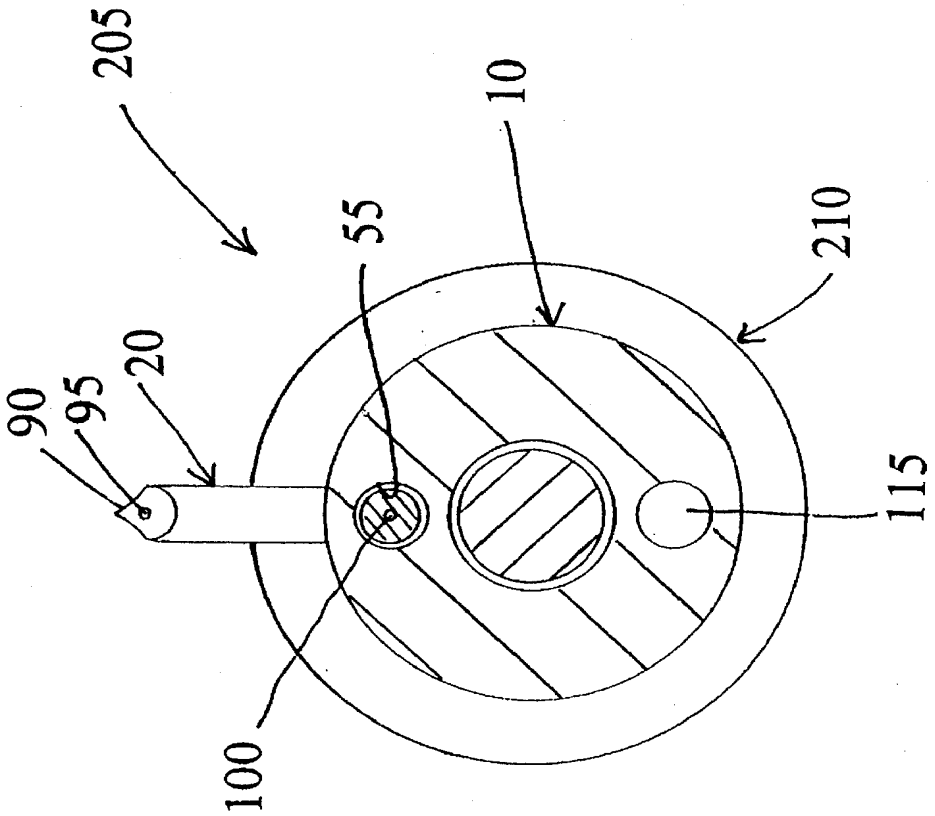


FIG. 19

CATHETER FOR DELIVERING THERAPEUTIC AND/OR DIAGNOSTIC AGENTS TO THE TISSUE SURROUNDING A BODILY PASSAGEWAY

FIELD OF THE INVENTION

The present invention relates generally to catheters. More particularly, the present invention relates to an improved catheter and to a method for using the same to deliver therapeutic and/or diagnostic agents to the tissue surrounding a bodily passageway. The present invention is particularly well suited to use in connection with percutaneous transluminal angioplasty procedures, where the direct administration of drugs to the angioplasty site may help to promote improved vascular healing and to reduce restenosis.

BACKGROUND OF THE INVENTION

The use of balloon catheters to enlarge artherosclerotic blood vessels, as well as to counteract narrowing in ureters, urethras, bile ducts, fallopian tubes and the like, is well known in the art. In transluminal angioplasty, for example, a coronary artery that has become blocked with plaque (i.e., an artherosclerotic blood vessel) is enlarged through the use of a balloon catheter. This procedure has been found to be a therapeutic alternative to the surgical removal of the plaque and/or to bypass surgery.

More particularly, the balloon angioplasty procedure is generally carried out as follows. First, a balloon catheter is positioned within the restricted segment of the blood vessel. Then the catheter's balloon is inflated with a fluid (e.g. a gas or liquid) so as to compress the plaque and thereby enlarge the central lumen of the blood vessel. In this way blood flow through the vessel can be increased.

Unfortunately, such dilation of an artherosclerotic blood vessel can often cause serious damage to the blood vessel, due to the trauma associated with dilation. In particular, it has been found that the dilated blood vessel frequently has an excessive healing response, such that the blood vessel's central lumen subsequently renarrows. This frequently occurs within as little as six months after the dilation procedure is conducted.

Experimental studies have shown that administering anti-platelet, anti-coagulant, anti-proliferative and/or anti-inflammatory drugs to the site of the trauma can regulate the healing response of the tissue. Unfortunately, these drugs have traditionally been administered to the patient systemically. As a result, it has generally been necessary to administer relatively high dosages to the patient in order to achieve the desired concentrations of the drugs at the site of the trauma. These high dosage levels have sometimes caused serious side effects in the patient.

It has been recognized that the controlled delivery of these therapeutic agents directly to the trauma site would allow the desired dosages to be administered to the damaged tissue, without the occurrence of systemic toxicity. In fact, it has been found that the controlled delivery of appropriate medication directly to the trauma site is one of the most effective means of reducing the excessive healing response that causes restenosis in the dilated blood vessels.

Consequently, to avoid the dangers of systemic toxicity, various devices have been proposed to deliver medication directly to the side wall of a blood vessel.

For example, balloon catheters have been constructed where the body of the balloon is formed out of a permeable membrane. As a result, when these balloon catheters are positioned within a restricted segment of a blood vessel and their balloons subsequently inflated with an appropriate medication-containing fluid, the medication-containing fluid will pass through the wall of the balloon and into the adjacent wall of the blood vessel. In this way the desired medication can be delivered directly to the site of the angioplasty. Unfortunately, however, it has also been found that these fluid-permeable balloon catheters must generally use a relatively high fluid pressure in order to properly inflate their balloons and eject their medication-containing fluid. This pressure is at a magnitude such that it tends to cause additional damage to the wall of the blood vessel, which in turn leads to further excessive vascular healing response and hence to additional renarrowing of the blood vessel.

In another attempt to provide the local delivery of medication directly to the dilation site, encapsulated drugs have been deposited directly onto the inner wall of the blood vessel during the angioplasty procedure using a heated balloon catheter system. And in another technique, drugs have been impregnated into a hydrophilic coating which is placed on the catheter's balloon, so that the drugs are applied to the surrounding tissue during balloon inflation. Additionally, wire and/or biodegradable stents have been developed which can be impregnated with drugs so as to provide local drug delivery when those stents are deployed at the angioplasty site. Furthermore, it has also been shown that the controlled delivery of a drug to the exterior of the blood vessel by surgical techniques can help inhibit the renarrowing process (i.e., restenosis).

Unfortunately, all of the prior art devices and methods heretofore used to deliver therapeutic agents directly to the angioplasty site have suffered from one or more significant deficiencies. Until now, none have been completely effective in administering measured amounts of a therapeutic agent directly to the damaged tissue in a dilated blood vessel.

OBJECTS AND SUMMARY OF THE INVENTION

Accordingly, a primary object of the present invention is to provide an improved catheter for delivering therapeutic and/or diagnostic agents directly to the tissue surrounding a bodily passageway or other hollow structure in order to improve healing, prevent restenosis and/or aid in diagnosis. Another object of the present invention is to provide an improved catheter that comprises at least one needle cannula for delivering medication to the tissue surrounding a bodily passageway. A further object of the present invention is to provide an improved balloon catheter for use in a transluminal angioplasty procedure, wherein the catheter can be used to deliver medication directly to the dilation site at any time during the angioplasty procedure.

Another object of the present invention is to provide an improved catheter for delivering drugs directly to the tissue surrounding a bodily passageway, wherein the catheter includes means for fixedly positioning the catheter in place within the bodily passageway prior to the delivery of drugs to the surrounding tissue.

And another object of the present invention is to provide an improved method for locally administering therapeutic and/or diagnostic agents directly to the tissue surrounding a bodily passageway or other hollow structure in order to improve healing, prevent restenosis and/or aid in diagnosis.

Still another object of the present invention is to provide

an improved method for locally administering medication to an angioplasty site.

These and other objects of the present invention are achieved through the provision and use of a novel catheter which is adapted to deliver therapeutic and/or diagnostic agents directly to the tissue surrounding a bodily passageway or other hollow structure.

More particularly, the novel catheter generally comprises an elongated body having a distal portion and a proximal portion, wherein the distal portion defines a distal surface; means for directing the catheter through a bodily passageway so that the distal portion of the catheter is disposed at a predetermined location within the bodily passageway; a lumen extending through the catheter's elongated body and opening on the catheter's distal surface; and a needle cannula having a distal portion and a proximal portion, wherein the distal portion of the needle cannula is adapted to pierce tissue and the proximal portion of the needle cannula is adapted to be connected to an appropriate source of therapeutic and/or diagnostic agents. The needle cannula is disposed within the lumen so that the needle cannula can be moved between (i) a first retracted position wherein the distal portion of the needle cannula is positioned within the distal portion of the catheter, just inboard of the catheter's distal surface, and (ii) a second extended position wherein the distal portion of the needle cannula is extended a predetermined distance outboard of the catheter's distal surface.

In a preferred embodiment of the present invention, the catheter further comprises a balloon fixedly and sealably secured to the distal portion of the catheter; and an inflation/deflation passageway extending through the catheter's elongated body, wherein the distal portion of the inflation/deflation passageway is in communication with the interior of the balloon, and the proximal portion of the inflation/deflation passageway is adapted to be connected to an appropriate source of inflation, whereby the balloon can be inflated or deflated on command.

The catheter is used as follows. First, the catheter's needle cannula is placed in its first retracted position. Then, with its balloon deflated, the catheter is advanced to a position within a bodily passageway so that the catheter's distal surface resides adjacent to the tissue which is to receive the desired therapeutic and/or diagnostic agents. Next, the balloon is inflated. As the balloon inflates, it engages the side wall of the bodily passageway, thereby dilating the passageway to the extent desired and fixedly positioning the catheter therein. As this occurs, the catheter's distal surface is brought into close engagement with the tissue which is to receive the therapeutic and/or diagnotic agents. With the catheter held firmly in position by the balloon, the needle cannula is advanced into its second extended position, whereby the distal portion of the needle cannula penetrates the tissue which is to receive the therapeutic and/or diagnostic agents. Then the agents are dispensed into the tissue. After the appropriate quantity of therapeutic and/or diagnostic agents have been administered to the tissue, the needle cannula is withdrawn back into its first retracted position, the balloon is deflated, and the catheter is withdrawn from the bodily passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects, features and advantages of the present invention will be more fully disclosed in, or rendered obvious by, the following detailed description of the preferred embodiments of the invention, which are to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:

FIG. **1** is a side view of a catheter which comprises a preferred embodiment of the present invention, wherein the catheter comprises a single needle cannula and a single balloon, and further wherein the catheter's needle cannula is shown in its second extended position, and the catheter's balloon is shown fully inflated;

FIG. **2** is a partial side view, in partial section, of the catheter shown in FIG. **1**, wherein the catheter's needle cannula is shown in its first retracted position;

FIG. **3** is a cross-sectional view of the catheter shown in FIG. **1**, taken along line **3—3** of FIG. **1**;

FIG. **4** is an enlarged side view of the proximal end of the needle cannula of the catheter shown in FIG. **1**;

FIG. **5** is a schematic cross-sectional view of a healthy blood vessel;

FIG. **6** is a schematic cross-sectional view of a diseased blood vessel, particularly illustrating the build-up of plaque about the central lumen thereof;

FIG. **7** is a view similar to that of FIG. **6**, except that the catheter of FIG. **1** has been positioned within the central lumen of the partially blocked blood vessel, with the catheter's needle cannula being in its first retracted position, and with the catheter's balloon being in its deflated state;

FIG. **8** is a view similar to that of FIG. **7**, except that the catheter's balloon has been inflated so as to dilate the blood vessel, and the catheter's needle cannula has been advanced into its second extended position so as to penetrate the tissue surrounding the vessel's central lumen;

FIG. **9** is a partial side view, in partial section, of a catheter which comprises an alternative embodiment of the present invention, wherein the catheter comprises a pair of needle cannulas and a single balloon, and further wherein the two needle cannulas are both shown in their second extended position, and the catheter's balloon is shown in its inflated state;

FIG. **10** is a cross-sectional view of the catheter shown in FIG. **9**, taken along line **10—10** of FIG. **9**;

FIG. **11** is a cross-sectional view similar to that of FIG. **10**, but illustrating a further alternative embodiment of the present invention wherein the two needle cannulas are positioned in circumferentially-spaced relationship to one another;

FIG. **12** is a side view of a catheter which comprises still another alternative embodiment of the present invention, wherein the catheter comprises a pair of needle cannulas and a pair of balloons, and further wherein one of the needle cannulas is shown in its second extended position and both of the catheter's balloons are shown in their inflated state;

FIG. **13** is a cross-sectional view of the catheter shown in FIG. **12**, taken along line **13—13** of FIG. **12**;

FIG. **14** is a side view of a catheter which comprises yet another alternative embodiment of the present invention, wherein the catheter comprises a single needle cannula and a single balloon, and wherein the catheter's needle cannula is shown in its second extended position and the catheter's balloon is shown fully inflated, and further wherein the catheter comprises tissue cutting means;

FIG. **15** is a side view of a catheter which comprises still another embodiment of the present invention, wherein the catheter comprises a pair of needle cannulas and no balloon, and further wherein the catheter's needle cannulas are both shown in their second extended position;

FIG. **16** is a cross-sectional view of the catheter shown in FIG. **15**, taken along line **16—16** of FIG. **15**;

FIG. **17** is a perspective view of a catheter which comprises yet another embodiment of the present invention, wherein the catheter comprises a single needle cannula and a single balloon, wherein the catheter's balloon extends completely around the distal portion of the catheter, and the needle cannula is adapted to exit the catheter on the proximal side of the balloon, and further wherein the needle cannula is shown in its second extended position and the balloon is shown fully inflated;

FIG. **18** is a side view of the catheter shown in FIG. **17**; and

FIG. **19** is a cross-sectional view of the catheter shown in FIGS. **17** and **18**, taken along line **19—19** FIG. **18**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Looking first at FIGS. **1–4**, a catheter **5** is shown which comprises a preferred embodiment of the present invention. Catheter **5** generally comprises an elongated body **10**, means **15** for directing the catheter through one or more bodily passageways to a desired site, a needle cannula **20**, and a balloon **25**.

Elongated body **10** generally comprises a distal portion **30** and a proximal portion **35**.

In the preferred embodiment of the invention, the means **15** for directing the catheter through one or more bodily passageways to a desired site generally comprise a central passageway **40** extending from distal portion **30** through proximal portion **35**. Central passageway **40** is adapted to slidably accommodate a guidewire **45** extending therethrough. Guidewire **45** is of the sort commonly used to direct a catheter through one or more bodily passageways such as blood vessels. More particularly, guidewire **45** is typically formed out of a strong flexible wire such that it can be passed through various bodily passageways to reach a remote site within a patient's body. Catheter **5** can then be loaded onto guidewire **45** and passed down the guidewire until it reaches the remote site. Movement of catheter **5** through these bodily passageways is facilitated by a blunt conical nose portion **50** (FIG. **1**) which is fitted onto distal portion **30**.

Catheter **5** also includes a lumen **55** that extends between distal portion **30** and proximal portion **35**. More particularly, lumen **55** opens on the catheter's distal surface **38** at an opening **65**. Preferably, opening **65** is located approximately 1 to 3 centimeters from the distal end **70** of nose portion **50**. Access to the proximal end of lumen **55** is provided via hub **75** (FIGS. **1** and **4**).

Needle cannula **20** is slidably disposed in lumen **55**. Needle cannula **20** comprises a distal portion **80** (FIGS. **1–3**) and a proximal portion **85** (FIGS. **1** and **4**). Distal portion **80** includes a tissue-piercing tip **90** (FIGS. **1** and **3**) and a dispensing port **95** (FIG. **3**). In the preferred embodiments of the invention, distal portion **80** is normally curved somewhat so that it will exit opening **65** at an angle of between about 30° and 90° with respect to distal surface **38**. An angle of about 45° is preferred in many applications. At the same time, needle cannula **20** is formed out of a resilient material so that it can deform to the extent necessary to allow it to be retracted back into lumen **55** in the manner hereinafter discussed in greater detail.

Dispensing port **95** is in fluid communication with proximal portion **85** of needle cannula **20** via the cannula's central lumen **100** (FIG. **3**). Proximal portion **85** extends through hub **75** and is adapted to be connected to dispensing means (not shown) of the sort well known in the art (e.g. a syringe or fluid pump), whereby therapeutic and/or diagnostic agents can be dispensed out of port **95** on command.

Needle cannula **20** is slidably disposed in lumen **55** so that it can move between a first retracted position (FIG. **2**) and a second extended position (FIGS. **1** and **3**). In its first retracted position, the needle cannula's tissue-piercing tip **90** is located inboard of the catheter's distal surface **38** so as to avoid damaging tissue during deployment of the catheter, as will hereinafter be disclosed in further detail. In its second extended position, the cannula's tissue-piercing tip **90** is located outboard of the catheter's distal surface **38** so as to permit the needle cannula's tip to penetrate the tissue defining and/or surrounding the bodily passageway in which the catheter is disposed, as will hereinafter be discussed in further detail.

As seen in FIGS. **1** and **4**, the proximal portion **85** of needle cannula **20** extends out of hub **75**. Proximal portion **85** includes calibrated graduations **105** (FIG. **4**) positioned along its outer surface. Graduations **105** are calibrated so as to indicate the extent to which the needle cannula's tissue-piercing tip **90** extends outboard of the catheter's distal surface **38**. This assists the surgeon in properly positioning tip **90** in the target tissue during use, as will hereinafter be discussed in further detail. A stop **110** is provided to limit the distal movement of needle cannula **20** relative to catheter body **10** and, therefore, to limit the extent to which tissue-piercing tip **90** can penetrate into any tissue located adjacent to the catheter.

Looking now at FIGS. **1–3**, catheter **5** also comprises the balloon **25**. Balloon **25** is fixedly and sealably secured to the catheter's distal portion **30**. Balloon **25** extends both longitudinally and circumferentially about at least a part of distal portion **30**.

An inflation/deflation passageway **115** (FIGS. **1–3**) extends from the catheter's distal portion **30** to its proximal portion **35**. Inflation/deflation passageway **115** includes an opening **120** (FIGS. **1** and **2**) located within distal portion **30** that communicates with the interior of balloon **25**. Inflation/deflation passageway **115** extends along the length of the catheter, from opening **120** in distal portion **30**, through distal portion **30**, and through proximal portion **35**. Inflation/deflation passageway **115** exits shaft **10** through a hub **125** (FIG. **1**). Hub **125** is adapted to be connected to appropriate inflation means (not shown) of the sort well known to those skilled in the art, whereby balloon **25** can be inflated or deflated on command.

It will be appreciated that balloon **25** may be inflated by the introduction of either gases or liquids into inflation/deflation passageway **115**. It will also be appreciated that liquids containing therapeutic and/or diagnostic agents may also be used to inflate balloon **25**, and that balloon **25** may be made of a material that is permeable to such therapeutic and/or diagnostic liquids, whereby such liquids may be ejected into adjacent bodily tissues during balloon inflation. In any event, balloon **25** is generally constructed so that it may be inflated to between 15 and 30 psi during use. In the preferred embodiment of the present invention, balloon **25** comprises an inelastic material.

As previously discussed, transluminal angioplasty is a technique which is frequently used to enlarge a blood vessel, such as a coronary artery, that has become occluded by the build-up of plaque. The use of the foregoing catheter **5** will now be discussed in the context of performing such a

procedure.

More particularly, and looking now at FIG. **5**, a typical healthy coronary artery **130** is shown. Artery **130** generally comprises an outside artery wall **135**, a layer of adventitial tissue **140**, the media **145**, and the intima **150**. These tissue structures are arranged in substantially concentric layers about a central lumen **155**. Contrastingly, in an artherosclerotic coronary artery **160** such as that illustrated in FIG. **6**, the central lumen **165** has been significantly reduced in diameter due to the build-up of plaque on the intima **170**.

Catheter **5** can be used to reopen the narrowed central lumen **165** of artery **160**. This is done as follows. First, a guidewire **45** is introduced into the arterial system of the patient at an appropriate location, e.g., the femoral artery. Then the guidewire is snaked through the patient's arteries until the distal end of guidewire reaches the narrowed central lumen **165** of artery **160**. Next the catheter **5** is mounted on the proximal end of the guidewire **45** and slid down the guidewire until it is positioned in the narrowed central lumen **165** of artery **160**, in the manner shown in FIG. **7**.

During the foregoing catheter insertion procedure, balloon **25** is in its deflated state, and needle cannula **20** is disposed in its first retracted position so that its tissue-piercing tip **90** is located just inboard of distal surface **38** (FIG. **2**). This allows the catheter to pass smoothly through the patient's arteries without damaging the surrounding tissue or impeding the movement of the catheter.

Once catheter **5** has been properly positioned within the reduced diameter lumen **165** of diseased coronary artery **160**, balloon **25** is inflated. This causes catheter **5** to engage and compact the plaque built up on the artery's intima **170**, in the manner shown in FIG. **9**. As a result, the artery's central lumen **165** is dilated. Of course, since balloon **30** is asymetrically disposed about the distal portion **30** of catheter **5**, at least some blood will continue to flow around the catheter even when the balloon **25** is fully inflated within the artery.

It will be appreciated that catheter **5** will be securely fixed in position in artery **160** when balloon **25** is fully inflated, with the plaque compacted and with the artery's central lumen **165** dilated. At the same time, the catheter's distal surface **38** will have been brought into direct engagement with intima **170**. At this point the surgeon may slide needle cannula **20** distally within lumen **55**, by pushing the needle cannula's proximal portion **35** distally into hub **75**, so that needle cannula **20** will move from its first retracted position (FIG. **2**) to its second extended position (FIGS. **1**, **3** and **8**). As this occurs, the needle cannula's tissue-piercing tip **90** will penetrate to the adjacent tissue. The surgeon may regulate the degree of penetration by observing the calibrated graduations **105** which are disposed on the proximal portion **85** of needle cannula **20**.

Advantageously, needle cannula **20** may be extended so as to position its dispensing port **95** in any one of the concentric tissue layers **140**, **145** and/or **170** disclosed in FIGS. **6–8**, and/or outside of those tissue layers and into the surrounding tissues and/or organs. It is to be appreciated that as needle cannula **20** is extended out of catheter **5** in this manner, the catheter will be held securely in position within the artery by its inflated balloon **25**. Once the catheter's tissue-piercing tip **90** has been properly positioned within the surrounding tissue, the surgeon may proceed to dispense a measured quantity of therapeutic and/or diagnostic agents into that tissue.

Once the desired therapeutic and/or diagnostic agents have been administered to the surrounding tissue, needle cannula **20** is withdrawn from its second extended position (FIGS. **1**, **3** and **8**) into its first retracted position (FIG. **2**). Then balloon **30** is deflated and catheter **5** withdrawn from the patient's body in ways well known in the art.

The catheter **5** described above constitutes a preferred embodiment of the present invention. As noted previously, it comprises a single needle cannula **20** and a single balloon **25**. It is to be appreciated, however, that various modification may be made to the foregoing catheter **5** without departing from the scope of the present invention.

For example, during some surgical procedures it may be necessary or desirable to deliver more than one type of therapeutic and/or diagnostic agent to the same tissue, or to deliver the same therapeutic and/or diagnostic agent to more than one location in the tissue. Accordingly, a catheter may be provided which comprises more than one needle cannula. More particularly, and looking now at FIGS. **9** and **10**, a catheter **175** is shown which comprises two needle cannulas **20A** and **20B** which are positioned within two lumens **55A** and **55B**. Needle cannulas **20A** and **20B** are substantially identical to the needle cannula **20** disclosed in FIGS. **1–4**, and lumens **55A** and **55B** are substantially identical to the lumen **55** disclosed in FIG. **1–4**. More particularly, needle cannula **20A** comprises a distal portion **80A**, a tissue-piercing tip **90A**, a dispensing port **95A**, and a central lumen **100A**, all substantially identical to the corresponding structures disclosed previously in connection with needle cannula **20**. Needle cannula **20B** similarly comprises a distal portion **80B**, a tissue-piercing tip **90B**, a dispensing port **95B** (not shown in FIGS. **9** and **10**, but shown in FIG. **11**) and a central lumen **100B**, all also substantially identical to the corresponding structures previously disclosed in connection with needle cannula **20**.

The two needle cannulas **20A** and **20B** are positioned one above the other in catheter body **10**, as shown in FIG. **10**. It will be appreciated that needle cannulas **20A** and **20B** may or may not be operated independently of each other, as preferred, but in any case they are each operated in substantially the same manner as previously disclosed in connection with the discussion of needle cannula **20** shown in FIGS. **1–4**. In this way, more than one therapeutic and/or diagnostic agent may be delivered to the same tissue, or the same therapeutic and/or diagnostic agent may be to more than one location in the tissue, either to different depths or into different tissue, as required.

Needle cannulas **20A** and **20B** may be disposed within the catheter's elongated body **10** in some relationship other than the stacked, radially-spaced arrangement shown in FIGS. **9** and **10**. For example, FIG. **11** shows a catheter **180** in which needle cannulas **20A** and **20B** are placed side-by-side, in a circumferentially-spaced relationship, rather than stacked in a radially-spaced relationship. Again, needle cannulas **20A** and **20B** may or may not be operated independently of each other, as preferred, but in any case they are each operated in substantially the same manner as previously disclosed in connection with the discussion of needle cannula **20** shown in FIGS. **1–4**.

It will also be appreciated that more than one balloon may be disposed about the distal portion of the catheter. More particularly, and looking now at FIGS. **12** and **13**, a catheter **185** is shown which comprises two needle cannulas **20A** and **20B** and two balloons **25A** and **25B**. Needle cannulas **20A** and **20B** are disposed in diametrically-opposed, equally-circumferentially-spaced relationship to one another (FIG. **13**). Similarly, balloons **25A** and **25B** are disposed in dia-

metrically-opposed, equally-circumferentially-spaced relationship to one another (FIGS. **12** and **13**).

Needle cannulas **20**A and **20**B are substantially identical to the needle cannula **20** disclosed in FIGS. **1–4**. More particularly, needle cannulas **20**A and **20**B are slidingly positioned within lumens **55**A and **55**B, respectively, which extend through catheter body **10**. Needle cannulas **20**A and **20**B include tissue-piercing tips **90**A and **90**B, respectively. Dispensing ports **95**A and **95**B are disposed in their respective tissue-piercing tips **90**A and **90**B, and communicate with central lumens **100**A and **100**B, respectively. Needle cannulas **20**A and **20**B may or may not be operated independently of one another, as preferred, but in any case they are each operated in substantially the same manner as the needle cannula **20** disclosed in connection with FIGS. **1–4**.

Balloons **25**A and **25**B are substantially identical to the balloon **25** disclosed in FIGS. **1–4**. More particularly, balloons **25**A and **25**B are disposed about the distal portion of catheter body **10** and communicate with inflation/deflation passageways **115**A and **115**B, respectively, via openings **120**A and **120**B, respectively. Balloons **25**A and **25**B may or may not be operated independently of one another, as preferred, but in any case they are each operated in substantially the same manner as the balloon **25** disclosed in connection with FIGS. **1–4**.

Thus it will be seen that with this embodiment of the present invention, the surgeon may inject therapeutic and/or diagnostics agents at diametrically-opposed, equally-circumferentially-spaced locations around the bodily passageway, while the catheter is held in place within the passageway with a pair of diametrically-opposed balloons.

It is sometimes necessary to use a catheter to sever and remove tissue from a bodily passageway, e.g. a blood vessel. In such a case, it may also be desirable to locally deliver therapeutic and/or diagnostic agents to the surrounding tissue at the same time that severing and removal is being effected. To this end, and referring now to FIG. **14**, a catheter **190** is shown which has tissue cutting and removal means **195** located in the distal portion **30** of the catheter. Tissue cutting and removal means **195** might comprise a Simpson arthrectomy device such as that marketed by Devices For Vascular Intervention Inc. (DVI) of Redwood many tissue cutting and removal devices of the sort well known in the art, as preferred. Catheter **190** includes a needle cannula **20** (shown in its second extended second position) and a balloon **25** (shown fully inflated). Needle cannula **20** and balloon **25** are substantially identical to the corresponding structures shown in FIGS. **1–4** and operate in a substantially identical manner. Catheter **190** is disposed within a bodily passageway in the same manner as has been previously disclosed in connection with the catheter **5** shown in FIGS. **1–4**. In this case, however, cutting means **195** may also be used in ways well known in the art to sever and remove tissue from the bodily passageway.

The catheter of the present invention may also be provided with one or more needle cannulas as indicated above but omit the provision of a balloon. More particularly, and looking now at FIGS. **15** and **16**, a catheter **200** is shown which comprises two needle cannulas **20**A and **20**B. Needle cannulas **20**A and **20**B are substantially identical to the needle cannula **20** shown in FIGS. **1–4**. More particularly, needle cannulas **20**A and **20**B are slidably positioned in lumens **55**A and **55**B, respectively, which extend through catheter body **10**. Needle cannulas **20**A and **20**B include tissue-piercing tips **90**A and **90**B, respectively. Dispensing ports **95**A and **95**B are disposed in their respective tissue-piercing tips **90**A and **90**B, and communicate with central lumens **100**A and **100**B, respectively. Needle cannulas **20**A and **20**B may or may not be operated independently of one another, as preferred, but in any case they are each operated in substantially the same manner as the needle cannula **20** previously disclosed in connection with FIGS. **1–4**.

Similar embodiments having 1, 3, 4 or more needle cannulas are also considered to be within the scope of the present invention.

Needle cannulas **20**A and **20**B may extend outwardly in diametrically-opposed, equally-circumferentially-spaced relationship to one another as seen in FIG. **16**, or they may be positioned about the circumference of the catheter in a manner similar to that depicted in FIGS. **10**, **11**, or **13**. Advantageously, the needle cannulas **20**A and **20**B are deployed in substantially the same manner as previously disclosed in connection with the needle cannula **20** of FIGS. **1–4**, except that needle cannulas **20**A and **20**B now provide the additional benefit of collectively anchoring the catheter **200** in place within a bodily passageway.

It is also to be appreciated that the new catheter may utilize a balloon having a configuration different than the balloon **25** shown in FIGS. **1–4**. More particularly, and referring now to FIGS. **17–19**, a catheter **205** is shown which comprises a needle cannula **20** and a balloon **210**.

Needle cannula **20** is substantially identical to the needle cannula **20** disclosed in FIGS. **1–4**. More particularly, needle cannula **20** is slidingly positioned within lumen **55** which extends through body **10**. Needle cannula **20** includes a tissue-piercing tip **90** and a dispensing port **95** which communicates with central lumen **100**. Needle cannula **20** is operated in substantially the same manner as the needle cannula **20** disclosed in FIGS. **1–4**.

Balloon **210** is disposed circumferentially about the entire circumference of the distal portion of catheter **210**. An inflation/deflation passageway **115** extends through catheter body **10** and communicates with the interior of balloon **210** through an opening **120**, whereby balloon **210** may be inflated or deflated on command.

Still other variations, modifications, alterations, changes, uses, and the like will occur to those skilled in the art in light of the foregoing description of the preferred embodiment of the invention. For example, the present invention may be used in those instances requiring fixed positioning of medication dispensing means within a bodily passageway other than blood vessels, e.g., ureters, urethras, bile ducts, fallopian tubes and the like.

What is claimed is:

1. A catheter for delivering therapeutic and/or diagnostic agents directly into tissue surrounding a bodily passageway, comprising:

an elongated body having a distal portion and a proximal portion, said distal portion including a distal surface;

means for directing said elongated body through said bodily passageway so that said distal portion is positioned at a predetermined location therein;

first and second lumens communicating between said distal surface and said proximal portion of said elongated body, said first lumen communicating with said distal surface through a needle exit opening disposed therein;

a needle cannula slidably disposed in said first lumen, said needle cannula comprising a distal portion and a proximal portion, said proximal portion being adapted to be connected to means for dispensing said therapeutic

and/or diagnostic agents;

said needle cannula being adapted for movement between (i) a first retracted position wherein said distal portion of said needle cannula is withdrawn inboard of said distal surface, and (ii) a second extended position wherein said distal portion of said needle cannula extends a predetermined distance outboard of said distal surface; and

a balloon fixedly and sealably secured to said distal portion of said elongated body and in fluid communication with said second lumen for dilating said bodily passageway when said balloon is inflated and compacting plaque that has been deposited in said passageway, said balloon extending both longitudinally and circumferentially along only a side portion of said distal portion of said catheter so as to be in opposing radial alignment with said needle exit opening such that when said balloon is fully inflated (i) fluid flow is not restricted through said bodily passageway, and (ii) said needle cannula may be extended said predetermined distance into said tissue surrounding said bodily passageway at a predetermined location.

2. A catheter according to claim **1** wherein said catheter comprises at least two lumens and at least two needle cannulas, wherein each of said needle cannulas is slidably disposed in one of said lumens.

3. A catheter according to claim **2** wherein said at least two lumens are radially aligned with one another.

4. A catheter according to claim **2** wherein said at least two lumens are circumferentially spaced from one another.

5. A catheter according to claim **1** wherein said catheter comprises at least two balloons and at least two inflation/deflation passageways, wherein each of said inflation/deflation passageways is in communication with the interior of one of said balloons.

6. A catheter according to claim **5** wherein said at least two balloons are circumferentially spaced from one another.

7. A catheter according to claim **6** wherein said catheter comprises at least two lumens and at least two needle cannulas, wherein each of said needle cannulas is slidably disposed in one of said lumens, and further wherein said lumens are circumferentially spaced from one another.

8. A catheter according to claim **1** further comprising tissue severing means disposed on a portion of said elongated body.

9. A method for delivering therapeutic and/or diagnostic agents directly into tissue surrounding a bodily passageway, said method comprising the steps of:

(1) providing a catheter comprising:

an elongated body having a distal portion and a proximal portion, said distal portion including a distal surface;

means for directing said elongated body through said bodily passageway so that said distal portion is positioned at a predetermined location therein;

a first lumen communicating between said distal surface and said proximal portion of said elongated body, said first lumen communicating with said distal surface through a needle exit opening disposed therein;

a needle cannula slidably disposed in said first lumen, said needle cannula comprising a distal portion and a proximal portion, said proximal portion being adapted to be connected to means for dispensing said therapeutic and/or diagnostic agents;

said needle cannula being adapted for movement between (i) a first retracted position wherein said distal portion of said needle cannula is withdrawn inboard of said distal surface, and (ii) a second extended position wherein said distal portion of said needle cannula extends a predetermined distance outboard of said distal surface; and

a balloon fixedly and sealably secured to said distal portion of said elongated body and in fluid communication with an inflation/deflation lumen for dialating said bodily passageway and compacting plaque that has been deposited therein, said balloon extending both longitudinally and circumferentially along only a side portion of said distal portion of said catheter so as to be in opposing radial alignment with said needle exit opening such that when said balloon is fully inflated (i) fluid flow is not restricted through said bodily passageway, and (ii) said needle cannula may be extended said predetermined distance into said tissue surrounding said bodily passageway at a predetermined location;

(2) positioning said needle cannula in its said first retracted position and placing said balloon in its deflated state;

(3) positioning said catheter in said predetermined location in said bodily passageway;

(4) inflating said balloon so as to fixedly position said catheter within said bodily passageway;

(5) moving said needle cannula from said first fully retracted position to said second extended position, whereby a distal end of said needle cannula penetrates tissue surrounding said bodily passageway;

(6) dispensing said therapeutic and/or diagnostic agents from said distal end of said needle cannula;

(7) moving said needle cannula from said second extended position back into said first retracted position;

(8) deflating said balloon; and

(9) removing said catheter from said bodily passageway.

10. A catheter according to claim **1** wherein said needle cannula comprises a curved distal portion adapted to project outwardly from said needle exit opening, when said needle cannula is in said second extended position, at an angle of between about 30 degrees and about 90 degrees with respect to said distal surface of said elongated body.

11. A catheter according to claim **10** wherein said angle is about 45 degrees.

12. A catheter according to claim **1** wherein said balloon comprises a material that is permeable to liquids containing said therapeutic and/or diagnostic agents, whereby such liquids may be ejected into adjacent bodily tissues during inflation of said balloon.

13. A catheter according to claim **1** wherein said balloon comprises an inelastic material.

14. A catheter according to claim **1** wherein said balloon is asymetrically disposed about said distal portion of said elongated body.

15. A catheter according to claim **1** wherein said proximal portion of said needle cannula comprises a plurality of calibrated graduations whereby the degree of penetration of said needle cannula into said tissue surrounding said bodily passageway may be determined.

16. A catheter according to claim **1** wherein said means for directing said elongated body through said bodily passageway comprise a guidewire adapted for insertion into and travel through said bodily passageway.

* * * * *

EXHIBIT 3

US005676653A

United States Patent [19]

Taylor et al.

[11] Patent Number: 5,676,653

[45] Date of Patent: Oct. 14, 1997

[54] **KINK-RESISTANT STEERABLE CATHETER ASSEMBLY**

[75] Inventors: **Kevin Taylor**, Reading; **Philip F. Latzgo**, Etters; **Timothy J. Lenihan**, Reading, all of Pa.

[73] Assignee: **Arrow International Investment Corp.**, Wilmington, Del.

[21] Appl. No.: **619,912**

[22] Filed: **Mar. 20, 1996**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 534,345, Sep. 27, 1995, which is a continuation-in-part of Ser. No. 495,356, Jun. 27, 1995, abandoned.

[51] **Int. Cl.**[6] **A61M 37/00**

[52] **U.S. Cl.** **604/95**; 604/280

[58] **Field of Search** 604/95, 22, 101–103, 604/264, 280; 606/33, 41

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,364,352 11/1994 Cimino et al. 604/95

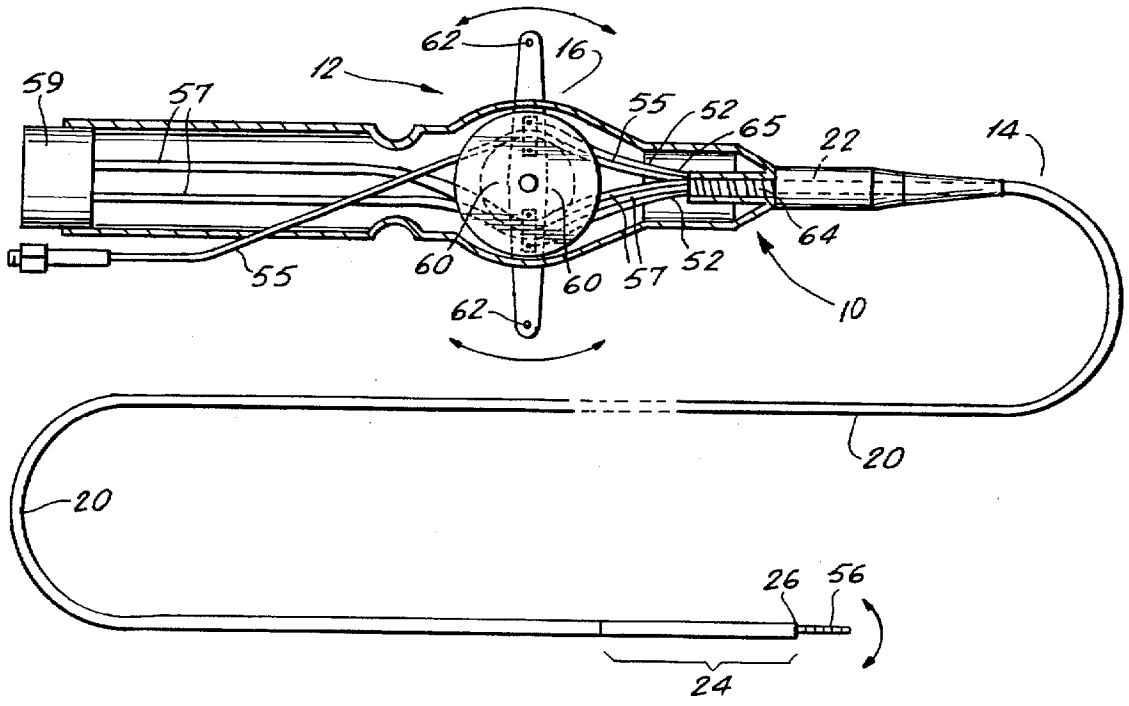
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Amster Rothstein & Ebenstein

[57] **ABSTRACT**

A kink-resistant steerable catheter assembly suitable for microwave ablation includes a handle, a catheter and a steering control. The catheter has (a) a flexible, torque-transmitting and axially incompressible proximal or body portion terminating in a proximal end attached to the handle, and (b) a flexible and axially compressible distal or tip portion terminating in a distal end. A coaxial cable is disposed in and extends through a large aperture in the catheter proximal portion, and a coaxial cable extension is generally centrally disposed in, substantially fills, and snugly extends through a large lumen in the catheter distal portion to reduce kinking. The control is disposed in and actuatable from the handle, for placing tension on one of a pair of steering wires while relaxing tension on the other of the pair of steering wires, thereby to bend the distal end of the coaxial cable extension toward the tensed one of the steering wires.

22 Claims, 6 Drawing Sheets



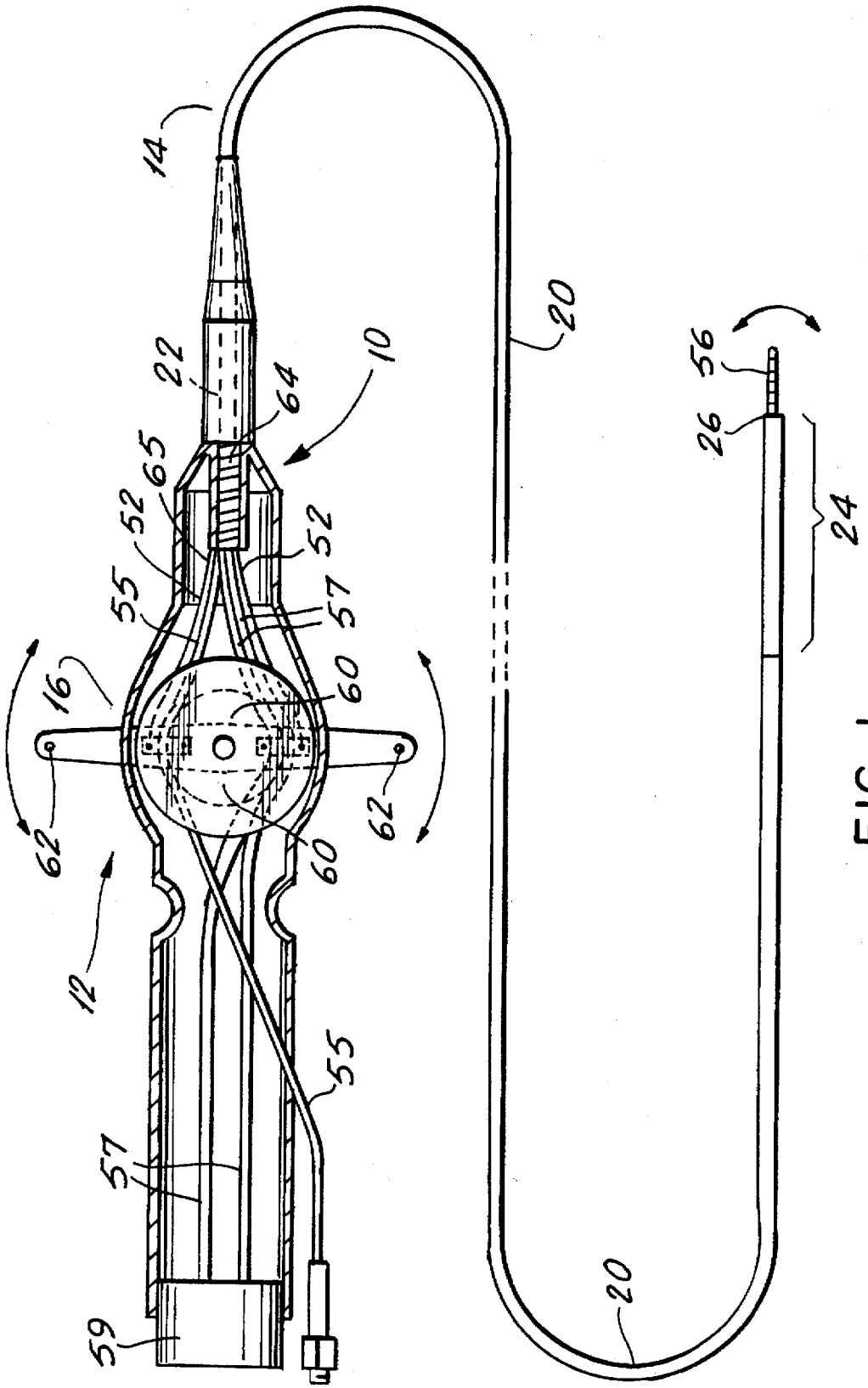


FIG. 1

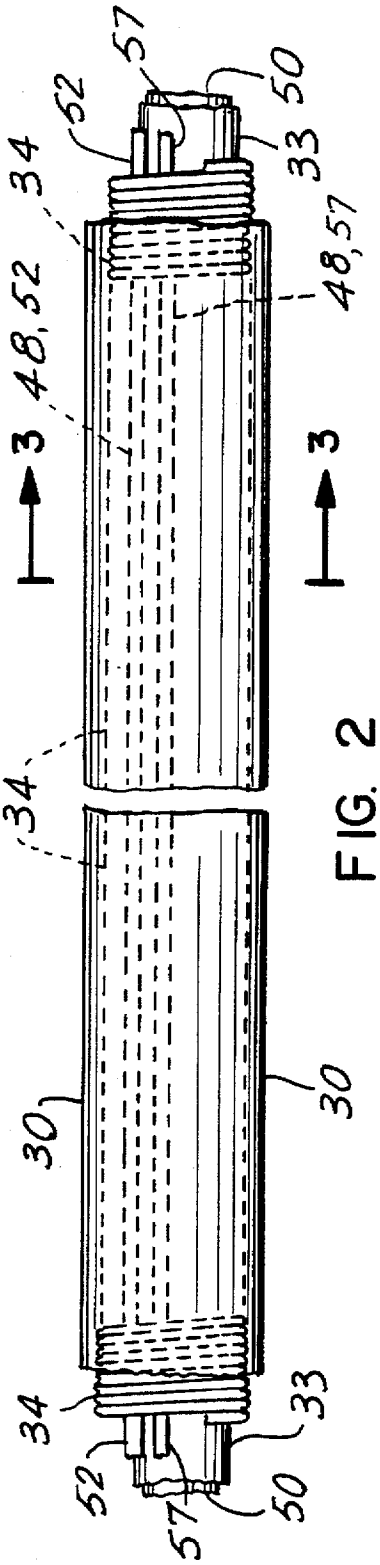

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FIG. 2

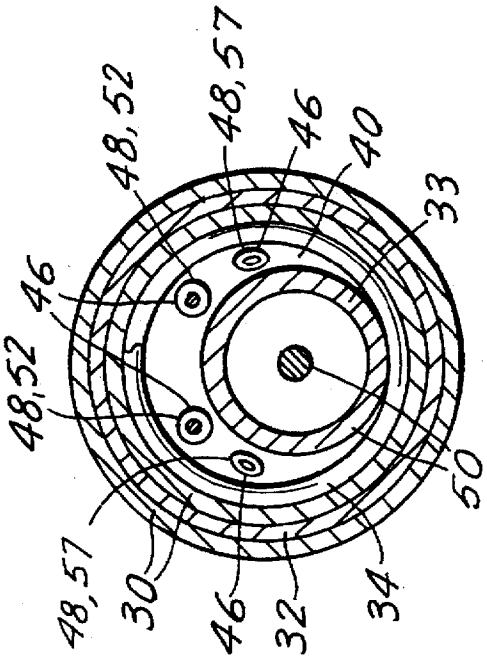
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FIG. 3

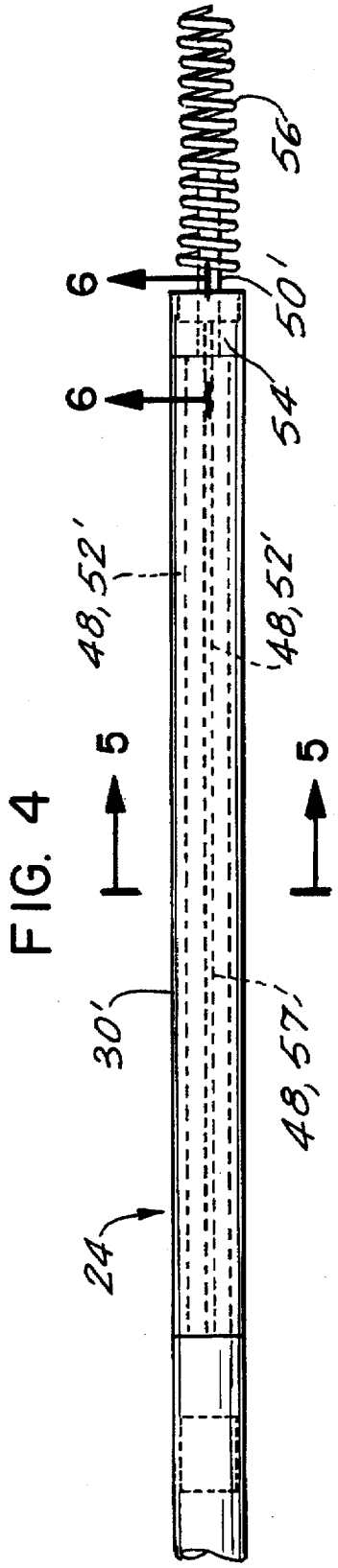


FIG. 4

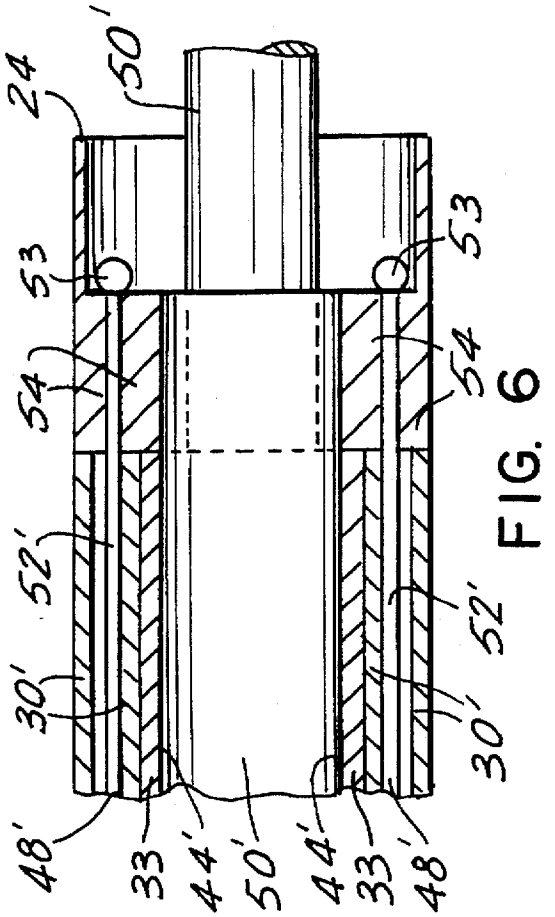


FIG. 6

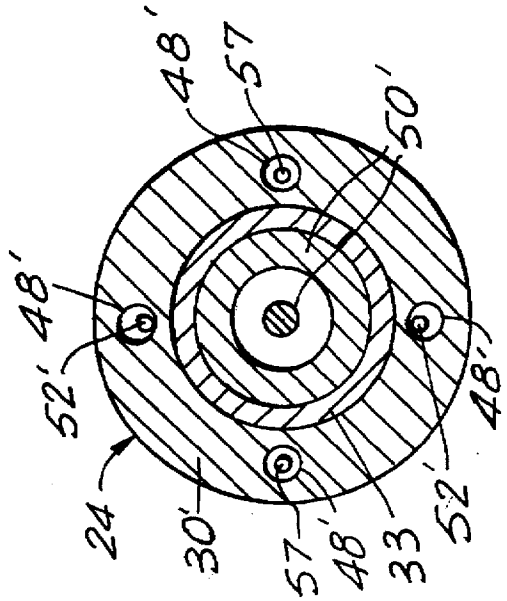


FIG. 5

FIG. 9

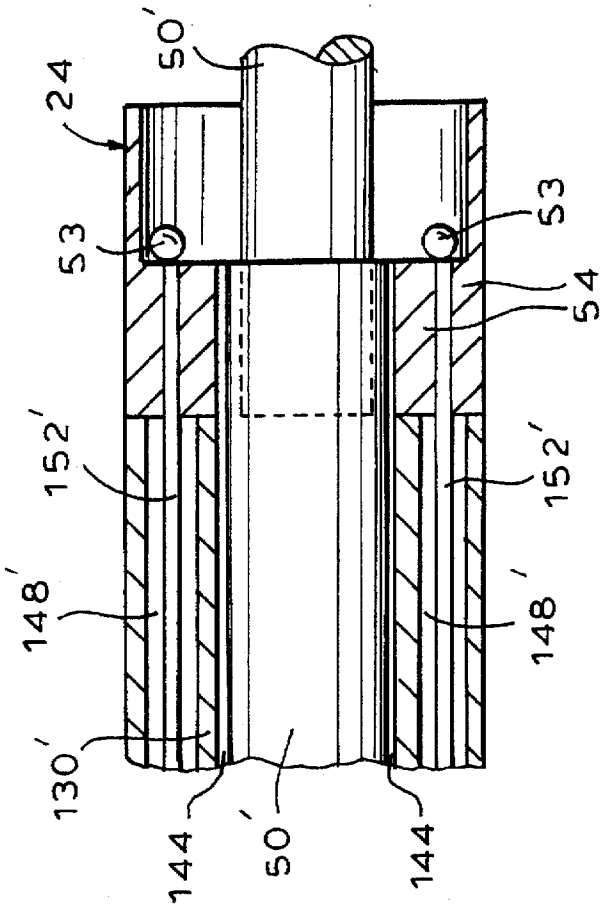


FIG. 8

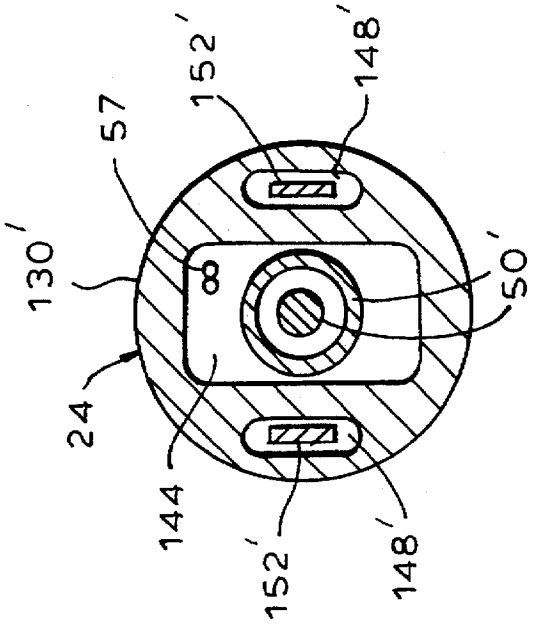


FIG. 7

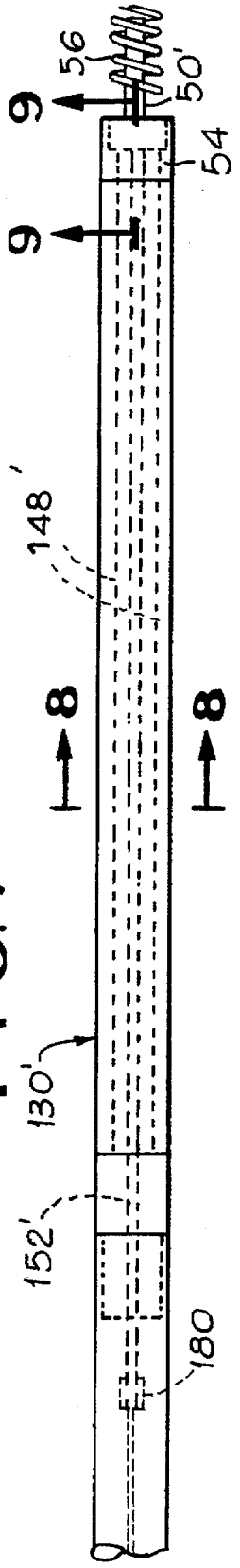
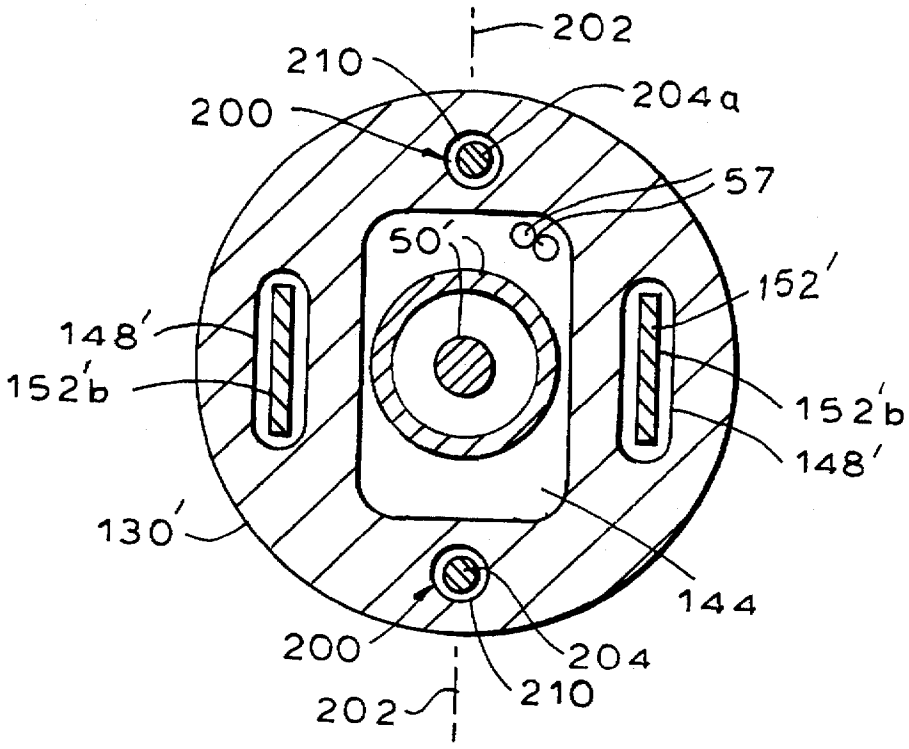


FIG. 10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148'
152'b
152'b
148'
130'
144
200
204
210
202

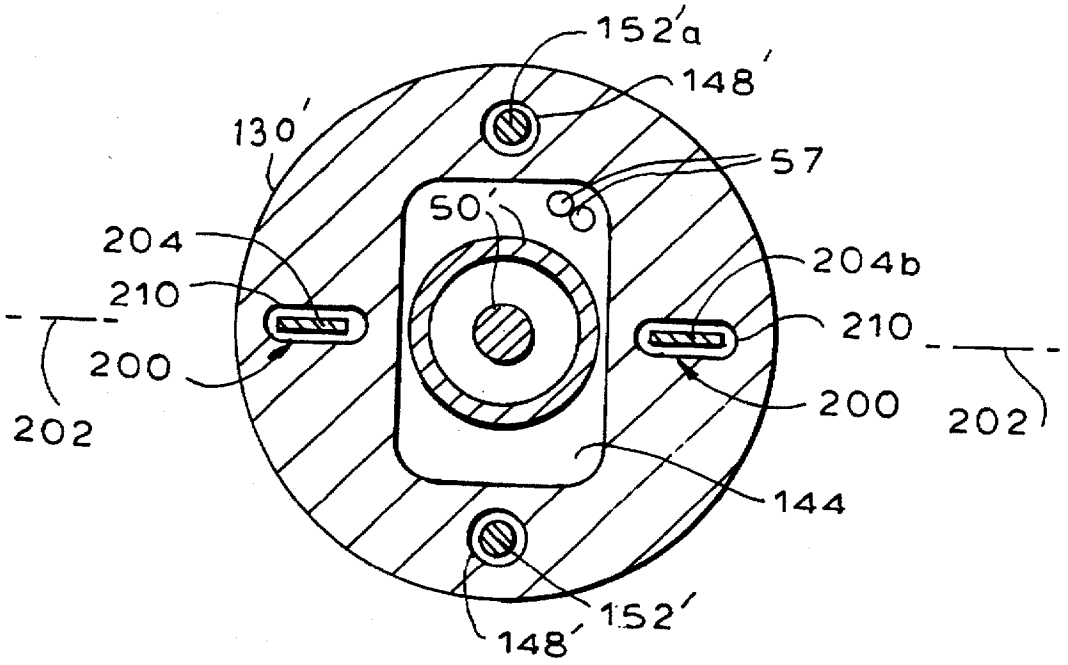
152'a
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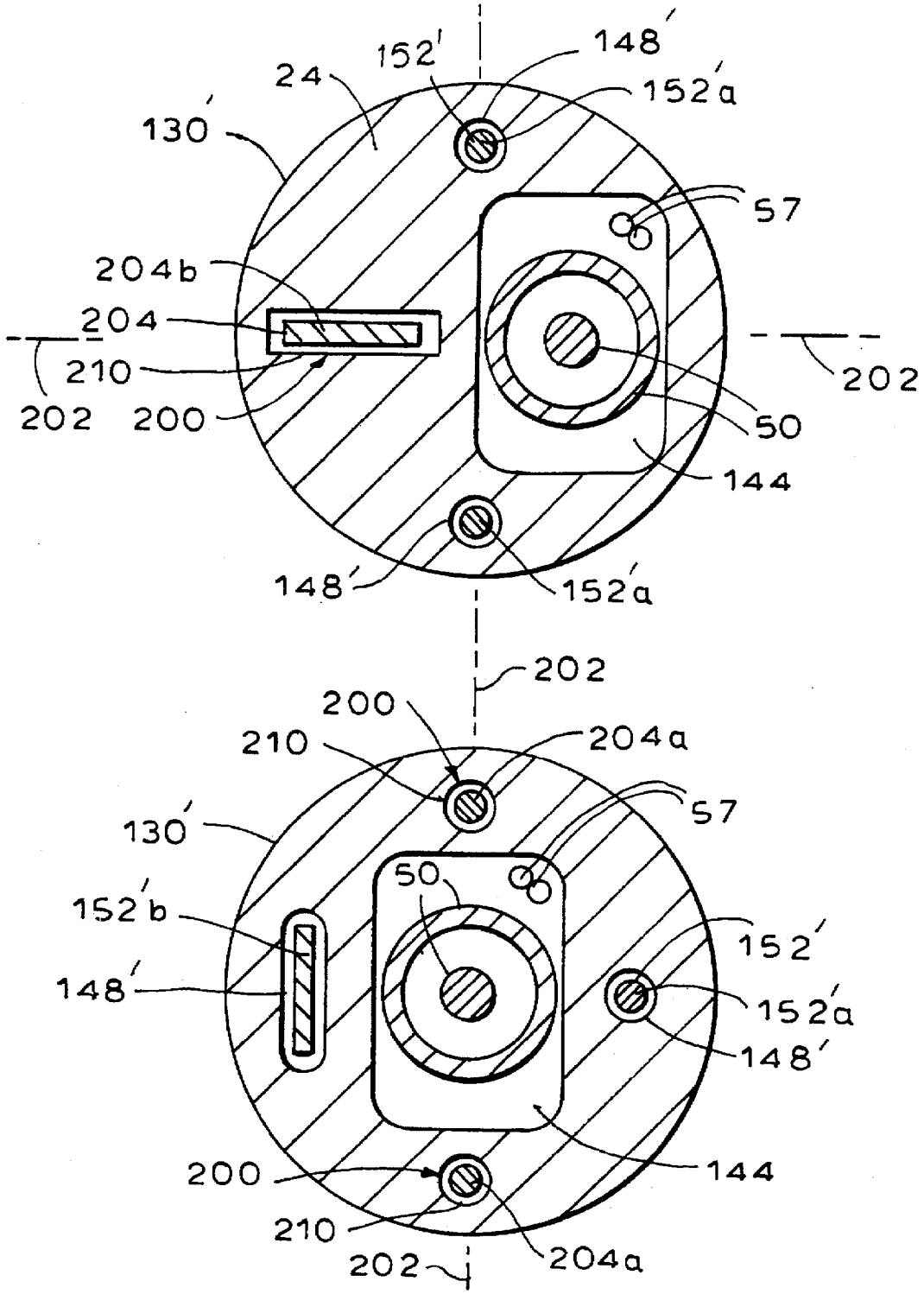
FIG. 11

FIG. 12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148'
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200
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204a
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FIG. 13

KINK-RESISTANT STEERABLE CATHETER ASSEMBLY

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of U.S. patent application Ser. No. 08/534,345, filed Sep. 27, 1995; itself a continuation-in-part of U.S. patent application Ser. No. 08/495,356, filed Jun. 27, 1995, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a steerable catheter assembly and, more particularly, to such a catheter assembly which is kink-resistant and suitable for use in microwave ablation.

In many medical procedures, it is necessary to position a catheter at a location within a patient's body. A typical emplacement for the distal end of a catheter might be within a ventricle of the heart, by way of the femoral artery. In so passing a catheter through the femoral artery, it is necessary to avoid obstructions, vessel junctions, and the like, and to make sharp turns to position the distal end of the catheter within the ventricle. Other medical procedures involve similar difficulties in placing a catheter.

Thus, steering mechanisms for catheters and other devices have been developed wherein the distal end of the device can be manipulated at will from a location outside the patient's body or outside the apparatus in which the device is placed. Catheter assemblies with the known steering mechanisms therein have not proven to be entirely satisfactory in use. For example, kinking of the catheter within the patient is a common problem, especially at the distal end of the catheter.

Typically, the physician is able to employ a conventional steerable catheter assembly which enables a soft distal region of a tubular shaft to deflect without altering the shape or stiffness of the proximal region of the shaft. Many of these steerable catheter assemblies utilize a pull wire system wherein a flat metal lead spring runs down the center of the soft distal portion of the tube and has a pair of pull wires attached to the very end thereof. By pulling on one pull wire, while the other pull wire is relaxed, the tip or front soft portion deflects. The centrally located metal lead spring acts as a biasing means to bias the catheter assembly to return the deflected tip to its original position and also to restrict the steering motion to one plane (that is, to opposite directions). See, for example, U.S. Pat. No. 5,336,182 and PCT International Application Publication No. WO 91/11213.

Another method uses a multi-lumen tube for the distal portion, the multi-lumen tube consisting of a central lumen with multiple off-center smaller lumens. The pull wires extend through the proximal section of the shaft and are diverted off-center into the off-center lumens at the beginning of the distal section. The pull wires are attached to the end of the distal section such that, when one wire is pulled and the other released, the tip of the tube is deflected in the direction of the pulled pull wire. A preferred method for tensioning pull wires utilizes a rotating, contoured pull wheel with two attached pull wires to deflect the distal tip in two directions. See, for example, U.S. Pat. No. 04,960,134, U.S. Pat. No. 5,318,525, and U.S. Pat. No. 5,328,467.

For the catheter steering to be effective, only the distal portion of the tube should deflect. Thus, the proximal portion of the catheter must be incompressible along its axial direction when a tension force is applied to the pull wires. This will keep the proximal portion of the catheter from bending and allow only the soft distal portion to bend and deflect. However, the catheter assembly must also remain flexible itself so it can be placed through tortuous blood vessels.

In addition to being steerable in a lateral direction, further positioning of known catheter assemblies is accomplished by rotating the catheter assembly as a whole about its longitudinal axis, typically by turning or twisting the proximal end of the catheter assembly. This exerts a torque along the length of the catheter assembly which is translated into a rotational motion at the distal end, thereby allowing a laterally deflected distal tip to be rotated.

A relatively new medical procedure requiring relatively exact placement of the catheter utilizes microwave (MW) energy to perform ablation rather than the conventional radio frequency (RF) energy. While RF energy may be transmitted along the length of a catheter by means of a relatively thin wire without damage to the other elements of the catheter, because of the nature of MW energy transmission and the continuing need to protect other elements of the catheter from the higher energies involved in MW transmission, it has been found necessary to utilize for MW transmission a coaxial cable rather than the thin wire used for RF transmission. For various reasons including the much greater diameter of a coaxial cable relative to a thin wire, the stiffness of the coaxial cable relative to a thin wire, and the limited space available within the interior of the catheter, the conventional steerable catheter assemblies do not lend themselves to microwave ablation.

Accordingly, it is an object of the present invention to provide a kink-resistant steerable catheter assembly.

Another object is to provide such a catheter assembly which employs a coaxial cable and is suitable for use in microwave ablation.

A further object is to provide such a catheter assembly which is relatively easy and inexpensive to manufacture, and easy to use and maintain.

SUMMARY OF THE INVENTION

It has now been found that the above and related objects of the present invention are obtained in a kink-resistant steerable catheter assembly comprising basically a handle, a catheter, and controller means. The catheter has (a) a flexible, torque-transmitting and axially incompressible proximal or body portion terminating in a proximal end attached to the handle, and (b) a flexible and axially compressible distal or tip portion terminating in a distal end. Controller means, disposed in and actuatable from the handle, place tension on one of a pair of steering wires while relaxing tension on the other of the steering wires, thereby to bend the distal end of the coaxial cable toward the tensed one of the steering wires.

More particularly, the proximal portion of the catheter includes an outer extrusion formed of a thin-walled, resilient tubing, and torque-transmitting means for transmitting torque along the catheter proximal portion. An axially incompressible means precludes both compression and kinking of the catheter proximal portion. A large aperture extends through the catheter proximal portion. At least a pair of relatively small flexible shafts, each defining a relatively small lumen, extend through the large aperture. A coaxial cable is disposed in and extends through the large aperture, and each of a pair of steering wires extends through a respective one of the small lumens and has a proximal end exiting a proximal end of the respective small lumen and entering the handle.

More particularly, the distal portion of the catheter includes an outer extrusion extension formed of a resilient tubing, and stiffly resilient biasing means for biasing the catheter distal portion to its home orientation. A large lumen extends through the catheter distal portion defined by the stiff biasing means, and at least a pair of relatively small lumen extensions are defined by the outer extrusion extension. A coaxial cable extension is generally centrally disposed in, substantially filling, and snugly extending through the large lumen, and each of a pair of steering wire extensions extends through a respective one of the small lumen extensions and has a distal end attached to the cable extension adjacent a distal end thereof.

In a preferred embodiment of the catheter proximal portion, the torque-transmitting means is a metal braid encapsulated by the tubing, and the axially incompressible means is an axially incompressible wire coil snugly fitted within an inner surface of the outer extrusion. The large aperture is defined by the inner surface of the coil. The small lumens are off-center in the large aperture, and the small lumens may be disposed on the same, side of the large aperture. In a preferred embodiment of the catheter distal portion, the biasing means is a relatively stiff material snugly fitted within the outer extrusion extension.

The catheter assembly is designed, configured and dimensioned especially for use in microwave ablation.

To limit movement of the catheter distal portion to a simple plane, the outer extrusion extension is formed of stiffly resilient material for biasing the catheter distal portion to its home orientation and resisting kinking of the catheter distal portion. A central large, rectangular lumen extends through the catheter distal portion defined by the material, and at least a pair of relatively small, off-center lumen extensions extend through the catheter distal portion defined by the material. A coaxial cable extension extends through the large lumen, and a pair of steering wire extensions, at least one of the steering wire extensions being of rectangular cross-section, extend through respective ones of the small lumen extensions, and have a distal end attached to the coaxial cable extension adjacent a distal end thereof.

In a preferred embodiment, the small lumen extensions are diametrically off-center relative to the large lumen and on opposite sides thereof. Preferably each steering wire extensions is of rectangular cross-section. Alternatively, at least one, and optionally both, of the steering wire extensions are circular cross-section. The flexible distal or tip portion of the catheter is axially compressible.

The present invention also encompasses a kink-resistant steerable catheter assembly which includes axially incompressible means for defining a flex plane intermediate the pair of steering wire extensions and enabling the steering wire extensions to bend the distal end to either side of the flex plane.

In a preferred embodiment, the flex plane is intermediate the small lumen extensions and the steering wire extensions therein and enables the steering wire extensions to bend the large lumen and the coaxial cable extension therein to either side of the flex plane. The incompressible means may include a spaced parallel pair of axially incompressible rods. The rods may be circular or rectangular in cross-section. The incompressible means may alternatively be a single incompressible rod of rectangular cross-section defining the flex plane.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and related objects, features and advantages of the present invention will be more fully understood by reference to the following detailed description of the presently preferred, albeit illustrative, embodiments of the present invention when taken in conjunction with the accompanying drawing wherein:

FIG. **1** is a top plan view of a kink-resistant steerable catheter assembly according to the present invention with portions of the handle removed to reveal details of internal construction;

FIG. **2** is a side elevational view of the proximal or body portion of the catheter, with portions thereof broken away to reveal details of internal construction;

FIG. **3** is a sectional view of the body portion, to an enlarged scale, taken along the line **3**—**3** of FIG. **2**;

FIG. **4** is a side elevational view of the distal or tip portion of the catheter;

FIGS. **5** and **6** are sectional views, to an enlarged scale, taken along the lines **5**—**5** and **6**—**6** of FIG. **4**;

FIGS. **7**, **8** and **9** are views similar to FIGS. **4**, **5** and **6**, but taken on an assembly with improved steering capabilities;

FIG. **10** is a view similar to FIG. **8** of a variant using circular incompressible support rods;

FIG. **11** is a view similar to FIG. **8** of a variant using flat rectangular incompressible support rods;

FIG. **12** is a view similar to FIG. **8** of a variant using a single flat rectangular incompressible support rod; and

FIG. **13** is a view similar to FIG. **8** of a variant using circular incompressible support rods, one flat rectangular steering wire extension, and one round steering wire extension.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawing, and in particular to FIG. **1** thereof, therein illustrated is a kink-resistant steerable catheter assembly according to the present invention, generally designated by the reference numeral **10**. The catheter assembly **10** is suitable for use in ablation therapy, and more particularly in microwave ablation therapy wherein the ablative energy is microwave energy. The catheter assembly **10** comprises a handle generally designated **12**, a catheter generally designated **14**, and controller means generally designated **16** and disposed in and actuatable from the handle **12**. Proceeding from the proximal end to the distal end, the catheter **14** is itself divided into a flexible, torque-transmitting and axially incompressible proximal or body portion **20** terminating in a proximal end **22** attached to the handle **12**, and a flexible and axially compressible distal or tip portion, generally designated **24**, terminating in a distal end **26**.

Turning now in greater detail to the proximal or body portion **20** of the catheter **14** and referring now to FIGS. **2** and **3** in particular, the catheter proximal portion **20** includes an outer extrusion **30** formed of a thin-walled, resilient tubing defining the outer surface of the catheter proximal portion **20**. The extrusion **30** is formed of any of the biocompatible resilient plastics typically used in catheters, with polyimide and a polyurethan available under the tradename PEBAX (from Atochem of Glen Rock, N.J.) being preferred materials.

Disposed intermediate the inner and outer surfaces of the tubing **30** is a torque-transmitting means **32** for transmitting torque along the catheter proximal portion so that a surgeon can turn the catheter distal portion **24** and thus the distal end **26** by suitable manipulation of the handle **12** and thus the catheter proximal portion **20**. A preferred torque-

transmitting means **32** is a metal braid encapsulated by the tubing **30** intermediate the inner and outer surfaces of the tubing **30**. A preferred metal braid **32** is formed of interleaved lengths of stainless steel and is disposed within the outer extrusion **30**.

The catheter proximal portion **20** additionally includes axially incompressible means **34** for precluding both compression and kinking of the catheter proximal portion **20**. A preferred incompressible means **34** is an axially incompressible wire coil snugly fitted within the outer extrusion **30**, and more particularly within the inner surface of the outer extrusion **30**. The coiled wire **34** may be manufactured by winding round wire around a mandrel so that the coils are adjacent and in contact with one another. The coil is then removed from the mandrel and allowed to relax. The inner diameter of the coiled wire should not exceed more than ten times the diameter of the stainless steel wire. Alternatively, flat wire may be used instead. A preferred wire is stainless steel. In any case, the wire coil is fed into the outer extrusion, the outer diameter of the coil being slightly less than the inner diameter of the outer extrusion **30**. A tight fit must exist between the wire coil **34** and the outer extrusion **30** in order to maintain the integrity of the wire coil **34**. If space were to exist intermediate the wire coil **34** and the outer extrusion **30**, the wire coils could overlap under compressive forces and thereby degrade the steering performance. It will be appreciated that the wire coil **34** enables the catheter proximal portion **20** to be very incompressible, but yet flexible. End caps (not shown) are attached to the outer extrusion **30** at both ends to secure the same to the ends of coil **34**, thereby to encapsulate and prevent extension of the wire coil **34**.

The combined thickness of the outer extrusion **30** (which includes therein the metal braid **32**) and the axially incompressible wire coil **34** is desirably kept to a minimum so that the outer diameter of the catheter meets a conventional size limitation (such as eight French size) and the outer diameter of a large aperture **40** within the combination is maximized, thereby to facilitate receipt therein and passage therethrough of the various other elements of the assembly, including the coaxial cable, wiring, etc.

The large aperture **40** extends through the catheter proximal portion **20** and is defined by the inner surface of the wire coil **34**. The remaining components of the catheter proximal portion **20** are disposed within this large aperture **40** as follows:

A coaxial cable **50** is disposed in and extends through the large aperture **40**. At least a pair of relatively small flexible shafts **46** (four being illustrated) extend through the large aperture **40**, each defining a relatively small lumen **48**. These shafts are preferably formed of PTFE (Teflon). Each of a pair of steering wires **52** (shown as a single line in FIG. 1) extends through a respective one of the small lumens **48**. Each of the steering wires **52** has a proximal end exiting the proximal end of its respective small lumen **48**, entering the handle **12**, and being functionally connected to the controller means **16** therewithin. As will be seen shortly, the steering wires **52** or extensions thereof are functionally associated with the coaxial cable **50** to enable steering thereof (and of the catheter distal portion **24**) in two directions, with the natural strong resiliency of the coaxial cable **50** tending to return the cable (and the catheter distal portion) to an original unbent and unstressed "home" position.

It will be appreciated by those skilled in the catheter art that the available space within the large aperture **40** has been exaggerated for expository purposes and typically there is little room to spare. Within the catheter proximal portion **20**, the large coaxial cable **50** and the relatively small flexible shafts **46** (two of which include the steering wires **52**) may be disposed in any compact orientation fitting within the large aperture **40**, and it is not necessary at this point that the steering wires **52** be disposed on opposite sides of the coaxial cable **50**. The large coaxial cable **50** and small lumens **48** are typically off-center in the large aperture **40**, the small lumens **48** typically being disposed on the same side of the large coaxial cable **50** within the large aperture **40**. The small shafts **46** (with their small lumens **48**) not occupied by the steering wires **52** may be used for thermocouples or additional electrical leads **57** extending to the distal end **26** of the catheter **14** and being electrically connected at the other end to a socket **59** in the handle **12**.

Turning now in greater detail to the catheter distal or tip portion **24**, and referring now to FIGS. **4–6** in particular, the catheter distal portion **24** includes an outer extrusion extension **30'** formed of a thin-walled, resilient tubing. The outer extrusion extension **30'** is preferably formed of a urethane/nylon blend of Durometer 40D available under the trade name PEBAX from Atochem of Glen Rock, N.J., although different materials may be used if desired. A stiffly resilient biasing means **33** is fitted within the inner surface of the outer extrusion extension **30'** for biasing the catheter distal portion **24** to its home orientation. The preferred material for the stiffly resilient biasing means **33** is a polyimide, although other stiffly resilient biasing materials may be employed. The stiffly resilient biasing means **33** cooperates with the coaxial cable extension **50'** to be described hereinbelow in biasing the catheter distal portion **24** to its home or unstressed orientation.

A large lumen **44** extends through the catheter distal portion **24** within the inner surface of the biasing means **33**, and at least a pair of relatively small lumen extensions **48'** (four being shown) extend through the outer extrusion extension **30'** and, more particularly, intermediate the inner and outer surfaces of the outer extrusion extension **30'**.

A coaxial cable extension **50'** is generally centrally disposed in, substantially fills, and snugly extends through the large lumen **44**. By way of example, the large lumen **44** may have an internal diameter of 0.055 inch, and the coaxial cable extension **50'** may have an external diameter of 0.052–0.054 inch. The snug match between the outer diameter of the coaxial cable extension **50'** and the inner diameter of the large lumen **44** precludes any kinking of the coaxial cable extension **50'** and therefore precludes any kinking of the catheter distal portion **24**. A pair of steering wire extensions **52'** extend through a respective pair of diametrically-opposed, off-center small lumen extensions **48'**. Each steering wire extension **52'** has a distal end functionally attached to an opposite side of the distal end of the coaxial cable extension **50'**.

More particularly, a washer-like member or plastic ring **54** is disposed adjacent the distal end of the catheter tip **24** with suitable apertures for (five being shown) passage therethrough of the coaxial cable extension **50'**, the two steering wire extensions **52'** (one steering wire extension **52'** to either side of the coaxial cable extension **50'**) and two additional components such or a thermocouple lead, etc., from the two small lumen extensions **48'**. The coaxial cable extension **50'** extends through and is secured (e.g., by gluing or the like) to a large central aperture of the washer **54**, and the steering wire extensions **52'** extend through a pair of small off-center apertures and are either secured to the washer **54** adjacent diametrically-opposed ends thereof or are, as illustrated, provided with enlarged distal heads **53**. The enlarged heads **53** at the end of the steering wire extensions **52'** may be

formed by silver solder beads, the beads preferably anchoring the distal tips of the wires **52'** to the washer or plastic ring **54**. Proximal pulling of a steering wire **52** will result in the corresponding steering wire extension **52'** tipping the washer **54** in the direction of that steering wire extension **52'**, and thus the steering of the catheter distal portion **24** in that direction. When the tension on that steering wire **52**, and thus that steering wire extension **52'**, is released, the catheter tip **24** will tend to resume its original or "home" orientation due to the combined action of the coaxial cable extension **50'** and the biasing means **33**.

The distal end **26** of the catheter assembly **10** is defined by an ablative electrode **56** in the form of a coiled wire electrically connected to an electrical source (not shown) by the coaxial cable extension **50'**, the coaxial cable **50**, and the electrical lead **55** illustrated in FIG. **1**.

Referring now to FIG. **1** in particular, the controller means **16** is disposed within and operable from outside the handle **12** for placing tension on one of the pair of steering wires **52** (and an associated extension **52'**) while relaxing tension on the other steering wire **52** (and its associated extension **52'**), thereby to tilt the washer **54** and bend the distal end of the coaxial cable extension **50'** towards the tensed one of the steering wire extensions **52'**. Thus, a contoured pull wheel **60** has the two steering wires **52** fastened thereto on opposite sides of the wheel **60** such that, as one wire goes into tension, the other wire relaxes. The pull wheel **60** is designed to allow for maximum deflection of the distal tip of the catheter assembly **10** with minimal travel of the pull wheel **60**. The contour of the pull wheel **60** is designed so that the steering wires **52** adjacent thereto are not exposed to any sharp angles which might cause the steering wires **52** to fatigue during operation or to break under tension. Indeed, it is contoured to allow the steering wires **52** to relax, when not in use, to avoid fatigue failure of the wires. The housing of the handle **12** encases all of the mechanical elements of the controller means **16** except for a pair of manually accessible grips **62** secured to the pull wheel **60** to effect limited rotation thereof.

In order to achieve effective steering, the steering wires **52** (and their extensions **52'**) must be adjusted initially to an appropriate tension. To this end, a screw **64** is provided for varying the spacing between the proximal end of the catheter **14** and the distal of the handle **12** so that the effective length of the catheter **14** (and indeed the entire catheter assembly **10**) may be increased to place additional tension on the steering wires **52** or reduced to relax the tension thereon.

As will be appreciated by those skilled in the art, means must be provided for the steering wires **52** to accumulate in the handle **12**. If the wires **52** have no space **65** in which to compress, they will fail at the point of bending after only minimal movements of the pull wheel **60** due to fatigue fracture. Inasmuch as handle-mounted controller means of this type are well known in the art (see, for example, PCT Publication WO91/11213 and U.S. Pat. No. 5,328,467), further details thereof need not be provided herein.

The design of the present invention enables a maximum amount of central material (i.e., coaxial cable) to be both disposed in the catheter and steered laterally, without the use of any flexible metal within the catheter distal portion for biasing the same. Indeed, the presence of the massive coaxial cable extension within the catheter distal end precludes the disposition of any flexible metal therein in order to aid in steering.

To summarize, the present invention provides a kink-resistant steerable catheter assembly, the assembly employing a coaxial cable and thus being suitable for use in microwave ablation. The catheter assembly is relatively easy and inexpensive to manufacture and easy to use and maintain.

It will be appreciated by those skilled in the steerable catheter art that it is highly desirable for the catheter motion transverse to its longitudinal axis to be limited at the distal end to a single plane. Thus it is intended that the steering wires **52, 52'** be diametrically opposed (that is, on opposite sides of the coaxial cable **50, 50'**) so as to be able to flex the coaxial cable in either one direction or the 180° opposite direction. It is therefore considered detrimental to operation of the catheter when either the steering wires or the resilient biasing means of the distal portion result in a movement of the catheter distal portion which is not within the intended plane.

It has now been found that the stiffly resilient biasing means **33** for biasing the catheter distal portion **24** to its home orientation and resisting kinking thereof frequently returns the catheter distal portion **24** to an orientation not within the intended plane of its operation. Referring now to FIGS. **7–9** in particular, this problem is at least partially overcome if the stiffly resilient biasing means **33** is eliminated. Notwithstanding the improvement in operation of the device effected by this modification, however, return of the coaxial cable extension **50'** to its home orientation remains problematic.

Referring now still to FIGS. **7–9**, therein illustrated is an improved embodiment of the present invention which achieves a positive return of the coaxial cable extension **50'** to its home orientation as well as effective restriction of the movement of the coaxial cable extension **50'** to a single plane. As noted above, the modified outer extrusion **130'** is preferably used without a stiffly resilient biasing means **33**. The modified outer extrusion extension **130'** defines a central rectangular lumen **44** and two additional off-center rectangular lumens **148'** which are of greatly smaller dimensions than the central lumen **144** and placed close to the outside of the catheter diameter, with the long edges of both the central and off-center rectangular lumens **144, 148'** being parallel to one another. The central rectangular lumen **144** and two off-center rectangular lumens **148'** have rounded corners to minimize abrasion of or by the elements within the lumens.

Disposed within each of the off-center rectangular lumens **148'** is a stainless steel steering wire extension **152'** of flat cross section. The use of flat steering wire extensions permits the distal tip to deflect in one plane without allowing the coaxial cable **50, 50'** to dictate the path of deflection. The flat wire **152'** is preferably from 0.006 inch×0.020 inch to 0.007×0.030 inch. The flat steering wire extensions **152'** are connected to the round steering wires **52** of the catheter proximal portion **20** by brazing or the like. The brazing joint of the two geometrically dissimilar wires **52, 152'** is located at **180** in the incompressible catheter body **20** adjacent the proximal end thereof. The long axis of each flat wire extension **152'** is aligned with the long axis of its respective off-center rectangular lumen **148'**. Eventually, as illustrated in FIG. **9**, the distal ends of flat wire extensions **152'** are secured to the washer **54** for deflecting the catheter distal portion **24**. While the flat wire extensions **152'** are illustrated as substantially smaller in both cross-sectional dimensions than the off-center lumens **148'**, it will be appreciated that a snugger fit is also possible. The larger width aspect (0.020 inch–0.007 inch), compared to the smaller thickness aspect (0.006 inch–0.007 inch), allows each of flat wire extensions **152'** to bend around its lateral axis (which is perpendicular to the plane in which the catheter distal tip needs to deflect)

and prevents bending around its longitudinal axis. Similarly, while the coaxial cable extension **50'** is illustrated as substantially smaller in both cross-sectional dimensions than central rectangular lumen **44**, it will be appreciated that a snugger fit is also possible as long as it enables the lumen **144** to house the coaxial cable extension **50'** as well as any required electrical leads **57**, which may include, for example, therecouple leads, pacing leads, etc.

With some loss of effectiveness relative to the use of two flat steering wire extensions **152'**, a hybrid catheter with one flat steering wire extension and one round steering wire extension may be used.

Each of the catheter embodiments described hereinabove utilizes a compressible distal or tip portion which may be manipulated by steering wires to deflect a solid inner member (i.e., a coaxial cable) in a single plane of motion, However, the durability and longevity of such catheters may not always be sufficient. The repeated compression of the distal portion during the deflection of the solid inner member (that is, the coaxial cable) may contribute to the shortening of the longevity of the distal portion. Additionally, the repeated compression of the distal portion directs a high level of compressive forces towards the incompressible proximal portion of the catheter with resultant adverse effects on the durability and longevity of the proximal portion. Accordingly, the present invention is also directed to a variant of the foregoing embodiments wherein the distal portion is longitudinally incompressible.

More particularly, as seen in FIGS. **10–13**, the incompressibility of the distal portion is achieved by the incorporation therein of longitudinally incompressible support means, generally designated **200**, for defining a flex plane designated **202** (illustrated in phantom line as coming out of the plane of the paper) intermediate the two steering wire extensions **152'** and enabling the steering wire extensions **152'** to bend the distal end to either side of the flex plane **202**. The disposition of the flex plane **202** intermediate the small lumen extensions **148'** and the steering wire extensions **152'** therein enables the steering wire extensions to bend the large lumen **144** and the coaxial cable extension **50'** therein to either side of the flex plane **202**.

Typically, the incompressible support means **200** includes a spaced parallel pair of incompressible support rods **204**. The incompressible support rods **204** may be circular in cross-section (rods **204***a* as illustrated in FIG. **10**) or flat rectangular in cross-section like a ribbon (rods **204***b* as illustrated in FIG. **11**). Alternatively, the incompressible support means **200** may be a single incompressible support rod **204***b* of flat rectangular cross-section (as illustrated in FIG. **12**). It will be appreciated by those skilled in the art that, where there are two incompressible support rods cooperatively defining therebetween a flex plane, both incompressible support rods **204** may be either circular or flat rectangular in cross-section and, indeed, one may be circular and the other may be flat rectangular. On the other hand, where there is but a single incompressible support rod **204**, that incompressible support rod **204***b* must be flat rectangular in cross-section in order to define by itself the flex plane. Where there are a pair of flat rectangular support rods **204***b* defining the flex plane **202**, the rods **204***b* are in end-to-end alignment.

Just as the incompressible support rods **204** may be either flat rectangular or circular in cross-section, the steering wire extensions **152'** (and the small lumen extensions **148'** thereabout) may be either circular in cross-section (wire extension **152'***a* as in FIG. **11**) or flat rectangular (wire extensions **152'***b* as in FIG. **10**). The use of a round steering wire extension **152'***a* or incompressible support rod **204***a* decreases the overall stiffness of the distal portion because it decreases the total cross-sectional area of the steering wire extension or incompressible support rod, thereby allowing for easier advancement of the catheter across areas where flexibility is necessary (such as the aortic valve).

Referring now to FIG. **10**, therein illustrated is a catheter similar to that illustrated in FIG. **8**, but also having in the distal portion a spaced parallel pair of incompressible support rods **204***a* of circular cross-section, one to either side of the large lumen extension **144**, for defining a flex plane **202**. It will be appreciated that the flex plane **202** extends intermediate the steering wire extensions **152'***b* and enable the steering wire extensions **152'***b* to bend the distal end to either side of the flex plane **202**.

Referring now to FIG. **11**, therein illustrated is a catheter also similar to that illustrated in FIG. **8** but also having in the distal portion a spaced parallel pair of incompressible support rods **204***b* of flat rectangular cross-section, one to either side of the large lumen extension **144**, for defining a flex plane **202** intermediate the circular steering wire extensions **152'***a*.

Referring now to FIG. **12**, therein illustrated is a catheter also similar to that illustrated in FIG. **8** but also having in the distal portion incompressible means **200** for defining a flex plane **202** intermediate the steering wire extensions **152'** and enabling the steering wire extensions **152'** to bend the distal end to either side of the flex plane **202**. The incompressible means **200** in this embodiment is a single incompressible support rod **204***b* of flat rectangular cross-section so as to enable flex of the distal portion towards either of the circular steering wire extensions **152'***a*. In this instance, the incompressible support rod **204***b* must be rectangular in cross-section, and not simply circular in cross-section.

Referring now to FIG. **13**, therein illustrated is a catheter wherein one steering wire extension **152'***b* is flat rectangular in cross-section and the other steering wire extension **152'***a* is round in cross-section, the two incompressible support rods **204***a* being circular in cross-section.

In each of the embodiments of FIGS. **10–13**, the small lumens **148'** for the flat rectangular steering wire extensions **152'***b* are rectangular in cross-section, and those for the circular steering wire extensions **152'***a* are circular in cross-section.

Typically, although not necessarily, the plane **202** defined by the incompressible support rod or rods **204** will extend through the coaxial cable extension **50'**. To facilitate the appropriate placement of the incompressible support rods **204**, the small lumen extensions **148'** and the contents **152'** thereof may be relocated within the extrusion extension **24**.

While the steering wire extensions **152'** are necessarily disposed in the small lumens **148'** to enable movement of the extensions within the lumens, the incompressible support rods **204** may either be disposed in appropriate small lumens **210** (whether circular or flat rectangular in cross-section) or the catheter may be formed with the rods **204** in situ. The ability to form the catheter with the incompressible support rods in situ enables manufacturing economies. The movement of the support rods **204** relative to the contiguous plastic of the catheter is so nominal than the contiguous plastic does not hinder the nominal movement of the support rods **204** relative thereto, even in the absence of a surrounding small lumen.

The incompressible support rods **204** are preferably constructed of non-malleable materials which in the finished

shape are both flexible and axially incompressible. Preferred materials are those available under the trade name NITINOL, a Ni/Ti alloy available from Raychem of Menlo Park, Calif.; 304 V STAINLESS STEEL, a vacuum heat-treated stainless steel available from Fort Wayne Metals of Fort Wayne, Ind.; and selected plastics; etc. The incompressible support rods are inserted into appropriate lumens therefore and then secured at their distal and proximal ends by RF (radio frequency) or like joining with an adjacent material. The incompressible support rods restrict the distal portion from absorbing the compressive forces generated by the steering wire extensions, thereby improving the durability of the distal portion.

To summarize, the presence of the incompressible support means improves the durability and longevity of the catheter while still permitting the distal portion to deflect in a single plane. Further, the presence of the incompressible support means enables the Durometer hardness of the extrusion to be decreased (for example, from about 40D units to about 35D units), thereby lowering the force which must be exerted in order to deflect the distal portion. Accordingly, this feature not only enhances the durability of the catheter, but also its ease of use.

Now that the preferred embodiments of the present invention have been shown and described in detail, various modifications and improvements thereon will become readily apparent to those skilled in the art. Accordingly, the spirit and scope of the present invention is to be construed broadly, and limited only by the appended claims, and not by the foregoing specification.

We claim:

1. A kink-resistant steerable catheter assembly comprising:

(A) a handle;

(B) a catheter having (a) a flexible, torque-transmitting and axially incompressible proximal or body portion terminating in a proximal end attached to said handle, and (b) a flexible and axially compressible distal or tip portion terminating in a distal end;

(a) said proximal portion of said catheter including:

(i) an outer extrusion formed of a thin-walled, resilient tubing,

(ii) torque-transmitting means for transmitting torque along said catheter proximal portion,

(iii) axially incompressible means for precluding both compression and kinking of said catheter proximal portion,

(iv) a large aperture extending through said catheter proximal portion,

(v) at least a pair of relatively small flexible shafts, each said small shaft extending through said large aperture and defining a relatively small lumen,

(vi) a coaxial cable disposed in and extending through said large aperture, and

(vii) a pair of steering wires, each of said steering wires extending through a respective one of said small lumens, and having a proximal end exiting a proximal end of said respective small lumen and entering said handle; and

(b) said distal portion of said catheter including:

(i) an outer extrusion extension formed of a resilient tubing,

(ii) stiffly resilient biasing means for biasing said catheter distal portion to its home orientation and resisting kinking of said catheter distal portion,

(iii) a large lumen through said catheter distal portion defined by said stiff biasing means,

(iv) at least a pair of relatively small lumen extensions defined by said outer extrusion extension,

(v) a coaxial cable extension generally centrally disposed in, substantially filling, and snugly extending through said large lumen, and

(vi) a pair of steering wire extensions, each of said steering wire extensions extending through a respective one of said small lumen extensions, and having a distal end attached to said cable extension adjacent a distal end thereof; and

(C) controller means, disposed in and actuatable from said handle, for placing tension on one of said steering wires while relaxing tension on the other of said steering wires, thereby to bend said distal end of said coaxial cable toward said tensed one of said steering wires.

2. The catheter assembly of claim **1** wherein said torque-transmitting means is a metal braid encapsulated by said tubing.

3. The catheter assembly of claim **1** wherein said axially incompressible means is an axially incompressible wire coil snugly fitted within an inner surface of said outer extrusion.

4. The catheter assembly of claim **3** wherein said large aperture is defined by said coil.

5. The catheter assembly of claim **1** wherein said small lumens are off-center in said large aperture.

6. The catheter assembly of claim **1** wherein small lumens are disposed on the same side of in said large aperture.

7. The catheter assembly of claim **1** wherein said biasing means is a relatively stiff material snugly fitted within said outer extrusion extension.

8. A kink-resistant steerable catheter assembly for use in microwave ablation, comprising:

(A) a handle;

(B) a catheter having (a) a flexible, torque-transmitting and axially incompressible proximal or body portion terminating in a proximal end attached to said handle, and (b) a flexible and axially compressible distal or tip portion terminating in a distal end;

(a) said proximal portion of said catheter including:

(i) an outer extrusion formed of a thin-walled, resilient tubing,

(ii) torque-transmitting means for transmitting torque along said catheter proximal portion, including a metal braid encapsulated by said tubing,

(iii) axially incompressible means for precluding both compression and kinking of said catheter proximal portion, including an axially incompressible wire coil snugly fitted within an inner surface of said outer extrusion,

(iv) a large aperture extending through said catheter proximal portion,

(v) at least a pair of relatively small flexible shafts, each said small shaft extending through said large aperture and defining a relatively small lumen, said small lumens being off-center in said large aperture, said small lumens being disposed on the same side of said large aperture,

(vi) a coaxial cable disposed in and extending through said large aperture, and

(vii) a pair of steering wires, each of said steering wires extending through a respective one of said small lumens, and having a proximal end exiting the proximal end of said respective small lumen and entering said handle; and

(b) said distal portion of said catheter including:

(i) an outer extrusion extension formed of a resilient tubing,

(ii) stiffly resilient biasing means fitted within said outer extrusion extension for biasing said catheter distal portion to its home orientation, said stiffly resilient biasing means being defined by a relatively stiff material snugly fitted within said outer extrusion extension to resist kinking of said catheter distal portion,

(iii) a large lumen through said catheter distal portion defined by said stiff material,

(iv) at least a pair of relatively small lumen extensions defined by said outer extrusion extension,

(v) a coaxial cable extension generally centrally disposed in, substantially filling, and snugly extending through said large lumen, and

(vi) a pair of steering wire extensions, each of said steering wire extensions extending through a respective one of said small lumen extensions, and having a distal end attached to said coaxial cable extension adjacent a distal end thereof; and

(C) controller means, disposed in and actuatable from said handle, for placing tension on one of said steering wires while relaxing tension on the other of said steering wires, thereby to bend said distal end of said coaxial cable toward said tensed one of said steering wires.

9. A kink-resistant steerable catheter assembly comprising:

(A) a handle;

(B) a catheter having (a) a flexible, torque-transmitting and axially incompressible proximal or body portion terminating in a proximal end attached to said handle, and (b) a flexible distal or tip portion terminating in a distal end;

(a) said proximal portion of said catheter including:

(i) an outer extrusion formed of a thin-walled, resilient tubing,

(ii) torque-transmitting means for transmitting torque along said catheter proximal portion,

(iii) axially incompressible means for precluding both compression and kinking of said catheter proximal portion,

(iv) a large aperture extending through said catheter proximal portion,

(v) at least a pair of relatively small flexible shafts, each said small shaft extending through said large aperture and defining a relatively small lumen,

(vi) a coaxial cable disposed in and extending through said large aperture, and

(vii) a pair of steering wires, each of said steering wires extending through a respective one of said small lumens, and having a proximal end and exiting a proximal end of said respective small lumen and entering said handle; and

(b) said proximal portion of said catheter including:

(i) a solid extrusion extension formed of resilient material for biasing said catheter distal portion to its home orientation and resisting kinking of said catheter distal portion,

(ii) a large, central lumen through said catheter distal portion defined by said extrusion extension,

(iii) at least a pair of relatively small, off-center lumen extensions through said catheter distal portion defined by said extrusion extension,

(iv) a coaxial cable extension extending through said large lumen, and

(v) a pair of steering wire extensions, at least one of said steering wire extensions being of rectangular cross-section, said steering wire extensions extending through a respective one of said small lumen extensions and having a distal end attached to said cable extension adjacent a distal end thereof; and

(C) controller means, disposed in and actuatable from said handle, for placing tension on one of said steering wires while relaxing tension on the other of said steering wires, thereby to bend said distal end of said coaxial cable toward said tensed one of said steering wires.

10. The catheter assembly of claim **9** wherein said small lumen extensions are diametrically off-center relative to said large lumen.

11. The catheter assembly of claim **9** wherein said small lumen extensions are disposed on opposite sides of said large lumen.

12. The catheter assembly of claim **9** wherein each of said steering wire extensions is of rectangular cross-section.

13. The catheter assembly of claim **9** wherein at least one of said steering wire extensions is of circular cross-section.

14. The catheter assembly of claim **9** wherein both of said steering wire extensions are of circular cross-section.

15. The catheter assembly of claim **9** wherein said flexible distal or tip portion of said catheter is axially compressible.

16. The catheter assembly of claim **9** wherein said flexible distal or tip portion of said catheter is axially incompressible.

17. A kink-resistant steerable catheter assembly comprising:

(A) a handle;

(B) a catheter having (a) a flexible, torque-transmitting and axially incompressible proximal or body portion terminating in a proximal end attached to said handle, and (b) a flexible distal or tip portion terminating in a distal end;

(a) said proximal portion of said catheter including:

(i) an outer extrusion formed of a thin-walled, resilient tubing,

(ii) torque-transmitting means for transmitting torque along said catheter proximal portion,

(iii) axially incompressible means for precluding both compression and kinking of said catheter proximal portion,

(iv) a large aperture extending through said catheter proximal portion,

(v) at least a pair of relatively small flexible shafts, each said small shaft extending through said large aperture and defining a relatively small lumen,

(vi) a coaxial cable disposed in and extending through said large aperture, and

(vii) a pair of steering wires, each of said steering wires extending through a respective one of said small lumens, and having a proximal end and exiting a proximal end of said respective small lumen and entering said handle; and

(b) said proximal portion of said catheter including:

(i) a solid extrusion extension formed of resilient material for biasing said catheter distal portion to its home orientation and resisting kinking of said catheter distal portion,

(ii) a large, central lumen through said catheter distal portion defined by said extrusion extension,

(iii) at least a pair of relatively small, off-center lumen extensions through said catheter distal portion defined by said extrusion extension,

(iv) a coaxial cable extension extending through said large lumen,

(v) a pair of steering wire extensions, said steering wire extensions extending through a respective

one of said small lumen extensions and having a distal end attached to said cable extension adjacent a distal end thereof; and

(vi) axially incompressible means for defining a flex plane intermediate said pair of steering wire extensions and enabling said steering wire extensions to bend said distal end to either side of said flex plane and;

(C) controller means, disposed in and actuatable from said handle, for placing tension on one of said steering wires while relaxing tension on the other of said steering wires, thereby to bend said distal end of said coaxial cable toward said tensed one of said steering wires.

18. The assembly of claim **17** wherein said flex plane is intermediate said small lumen extensions and said steering wire extensions therein and enables said steering wire extensions to bend said large lumen and said coaxial cable extension therein to either side of said flex plane.

19. The assembly of claim **17** wherein said incompressible means includes a spaced parallel pair of axially incompressible rods.

20. The assembly of claim **19** wherein said axially incompressible rods are circular in cross section.

21. The assembly of claim **19** wherein said incompressible rods are rectangular in cross section.

22. The assembly of claim **17** wherein said incompressible means is a single incompressible rod of rectangular cross-section defining said flex plane.

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